Freedom Of Information (FOI) Report

Outcome Dose Dui	ration	PT	Report Source	Product	Role	Manufacturer	Route
Death		Cerebrovascular Accident	Health	Adderall	PS		ORAL
20 MG TID PO 3	3 YR		Professional Company Representative	Unknown	С		
	R Number ler:Fema	: 3015328-XReport Type:Direct le I/FU:I	Company Re	port #			
Outcome Dose Dui	ration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10 MG AT	acton	Rash Papular		Adderall 10	PS		
8:00AM & NOON		Rash Pruritic					
Date:01/05/98ISB Age:35 YR Geno		: 3014451-3Report Type:Exped: le I/FU:I	ited (15-DaCompany Re	port #USA000476			
	cation	PT	Report Source	Product	Role	Manufacturer	Route
Outcome Dose Dui		Blood Thyroid Stimulating	Consumer	Synthroid	PS		
Dose Dui Other				Synthroid	SS		
Dose Dui		Hormone Increased					

Date:01/06/98ISR Number: 4517561-4Report Type:Direct Age: Gender: I/FU:I Company Report #USP 080946

Outcome		РТ	Report Source	Product	Role	Manufacturer	Route
Dose TABLET	Duration	Medication Error		Adderall	PS	Richwood	
	98ISR Number Gender:Male	: 3035591-9Report Type:Ex I/FU:I	pedited (15-DaCompany Re	eport #98021301			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 3 DAY	Duracion	Chest Pain	Health	Adderall	PS		ORAL
		Dry Mouth Hypertension Insomnia Mydriasis Respiratory Rate Increased Tachycardia	Professional pedited (15-DaCompany Re	eport #98021801			
Age:9 YR	Gender:Male						
Outcome Hospitalizat Initial or 1 Other		PT Drug Level Above Therapeutic Hallucination, Tactile Hypersensitivity Nervousness					
22-Aug-2005 Page: 1	10:34 AM						

Freedom Of Information (FOI) Report

			omotor Hyperactivity otic Disorder					
Dose	Duration			Report Source	Product	Role	Manufacturer	Route
				Health	Adderall	PS	Shire Richwood	ORAL
PO BID	1 I	AY		Professional	Dimetapp	SS		
Date:03/02/9 Age:	98ISR Numb Gender:Fe		250-XReport Type:Period I/FU:I	ic Company Repor	t #9703141			
-			_,	Dement Course	Duaduat	Dele	Manufacture	Dauta
Outcome Dose	Duration	PT		Report Source	Product	ROIE	Manufacturer	Route
Other 50.00 MG		Dry M	outh	Consumer	Zoloft Tablets	PS		ORAL
TOTAL;DAILY	;0							
RAL								
ORAL					Adderall	SS		ORAL
					Oral Contraceptives	С		
Date:03/09/9 Age:48 YR			195-5Report Type:Expedi I/FU:I	ted (15-DaCompany Repor	t #98030601			
Outcome Dose	Duration	PT		Report Source	Product	Role	Manufacturer	Route
Hospitaliza 10 TO 20 MG	tion -		rovascular Accident	Health	Adderall	PS		ORAL
Initial or 1 PER DAY Other	-	ON		Professional				
Date:03/30/9 Age:	98ISR Numb Gender:Ma		065-4Report Type:Period I/FU:I	ic Company Repor	t #US98022			
Outcome	Duration	PT		Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Alope	cia Plucking	Health Professional	Adderall	PS		

	98ISR Number Gender:Male	: 3153642-8Report Type:Periodi I/FU:I	ic Company Repor	t #97030401			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Leukocytosis Pharyngitis	Health Professional	Adderall Depakote	PS C		
125 MG TID		11111 1119 - 0 - 0	110105510441	Departoce	C		
Date:04/09/9 Age:13 YR		: 3153645-3Report Type:Periodi I/FU:I	ic Company Repor	:t #97031201			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other HAS TAKEN FO		Alopecia	Health	Adderall	PS		ļ
8 YEARS	8 YR		Professional				
	98ISR Number Gender:Male	: 3153646-5Report Type:Periodi I/FU:I	ic Company Repor	:t #97032501			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat ONE TABLET		Diabetes Mellitus	Health	Adderall 10	PS		ORAL
Initial or F DAILY Other	Prolonged		Professional				

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:04/09/98ISR Number: 3153647-7Report Type:Periodic Company Report #97041101 Gender:Female Aqe:3 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Other Hallucination Health Adderall 10 PS ORAL 10 MG ORAL Muscle Twitching Professional SINGLE DOSE Pyrexia 1/14/97 10 MG Date:04/09/98ISR Number: 3153649-0Report Type:Periodic Company Report #97042201 Age:10 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Other Chills Health Adderall 5 PS ORAL 5MG TABLETS Hallucination Professional ORAL EACH AM Date:04/09/98ISR Number: 3153650-7Report Type:Periodic Company Report #97042301 Gender:Female Aqe:17 YR I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hyperbilirubinaemia Adderall 10 PS ORAL Other Health 10 MG ORAL Professional TWICE A DAY Date:04/09/98ISR Number: 3153651-9Report Type:Periodic Company Report #97050601 Age:23 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Other Liver Function Test Health Adderal 10 PSORAL 10 MG

		Abnormal	Professional	Warfarin	С	
Date:04/09/9 Age:	98ISR Number Gender:Male	r: 3153653-2Report Type:Period I/FU:I	lic Company	Report #97050701		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 10 MG ORAL		Agitation	Health	Adderall 10	PS	ORAL
TABLETS		Depression	Professional			
Date:04/09/9 Age:	98ISR Number Gender:Fema	r: 3153654-4Report Type:Period ale I/FU:I	lic Company	Report #97052601		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other 10 MG ORAL	Duration	Menstrual Disorder	Health	Adderall 10	PS	ORAL
QD			Professional			
	98ISR Number Gender:Male	: 3153657-XReport Type:Period I/FU:I	lic Company	Report #97060101		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 20 MG ORAL	Duración	Orthostatic Hypotension	Other	Adderall 20	PS	ORAL
BID	3 DAY					

					e Event Reporting Syste Df Information (FOI) Re		2S)	
Date:04/09/9 Age:37 YR		er: 3153658-1Report Type:Periodi male I/FU:I	ic	Company Repor	t #97060501			
Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Dystonia	Health		Adderall 20	PS		ORAL
20 MG ORAL EVERY TWO			Profess	sional				
HOURS	2 WK				Prozac	С		
Date:04/09/9 Age:9 YR	98ISR Numbe Gender:Fem	er: 3153661-1Report Type:Periodi male I/FU:I	ic	Company Repor	t #97061701			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other ORAL	Duración	Albuminuria	Health		Adderall	PS		ORAL
			Profess	ional				
Date:04/09/9 Age:	98ISR Numbe Gender:	er: 3153663-5Report Type:Periodi I/FU:I	ic	Company Repor	t #97070801:			
Outcome	December	PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other OBAL	Duration	Photosensitivity Reaction	Health		Adderall	PS		ORAL
ORAL			Profess	sional				
Date:04/09/9 Age:	98ISR Numbe Gender:	er: 3153664-7Report Type:Periodi I/FU:I	ic	Company Repor	t #97071701:			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other	Duracion	Stomatitis	Health Profess		Adderall	PS		

	8ISR Number: Gender:Male	: 3153666-0Report Type:Periodic I/FU:I	c Company Repor	t #97081101		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other ORAL	Duración	Acne	Health	Adderall	PS	ORAL
		Hyperbilirubinaemia	Professional			
	8ISR Number: Gender:Male	: 3153667-2Report Type:Periodic I/FU:I	c Company Repor	t #97081102		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other ORAL, TWICE	Duración	Glycosuria	Health	Adderall 20	PS	ORAL
DAILY	12 MON	Hyperglycaemia	Professional			
	8ISR Number: Gender:Male	: 3153669-6Report Type:Periodic I/FU:I	c Company Repor	t #97081501		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other ORAL 20 MG	Duración	Liver Function Test	Health	Adderall	PS	ORAL
AM, 10 MG P	M 2 WK	Abnormal	Professional			

			erse Event Reporting om Of Information (FO		
Date:04/09/98ISR Numk Age: Gender:Ma	per: 3153670-2Report Type:Per le I/FU:I	riodic Company R	eport #97082701		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duratior Hospitalization - 10 MG ORAL	Asthma	Health	Adderall 10	PS	ORAL
Initial or Prolonged ONCE DAILY 4 I Other	DAY	Professional			
Date:04/09/98ISR Numk Age:12 YR Gender:Ma	er: 3153671-4Report Type:Per le I/FU:I	riodic Company R	eport #97083001		
Outcome Dose Duratior	PT	Report Source	Product	Role Manufacturer	Route
Dose Duratior Other 10 MG ORALLY	Convulsion	Health	Adderall 10	PS	ORAL
PER DAY		Professional			
Date:04/09/98ISR Numk Age:18 YR Gender:Ma	er: 3153673-8Report Type:Per le I/FU:I	riodic Company R	eport #97091801		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duratior Required 3 DAY	Haemolysis	Health	Adderall	PS	ORAL
Intervention to Prevent Permanent Impairment/Damage	Hyperbilirubinaemia	Professional			
Date:04/09/98ISR Numk Age:8 YR Gender:Ma	per: 3153941-XReport Type:Per le I/FU:I	riodic Company R	eport #97092401		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duratior Other 10 MG ORAL	Keratoconjunctivitis	Health	Adderall	PS	ORAL
	Sicca DAY	Professional			

	98ISR Number Gender:Fema	: 3153943-3Report Type:Periodi le I/FU:I	ic Company Repor	t #97100601		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 40 MG ORAL	Duración	Coma	Health	Adderall 20	PS	ORAL
EACH DAY	2 MON	Convulsion	Professional			
	98ISR Number Gender:Male	: 3153945-7Report Type:Periodi I/FU:I	ic Company Repor	t #97100701		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other ADDERALL 10	Duración	Grand Mal Convulsion	Health	Adderall 10	PS	ORAL
MG BID			Professional			
Date:04/09/9 Age:11 YR		: 3153947-0Report Type:Periodi I/FU:I	ic Company Repor	t #97102001		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 10 MG ORAL	Duración	Syncope	Health	Adderall 10	PS	ORAL
BID			Professional			

					FDA - Adver	se Event Reporting Sys	stem (AER	נS )	
					Freedom	Of Information (FOI)	Report		ļ
									ļ
Date:04/09/ Age:36 YR	98ISR Nur Gender:N		3153949-4Report Type:Period I/FU:I	lic	Company Repo	ort #97102301			
Outcome			PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other 10MG ORAL	Duratio		Grand Mal Convulsion	Health		Adderall	PS		ORAL
BID	2	WK		Profess	ional				
Date:04/09/ Age:	98ISR Nur Gender:I		3153950-0Report Type:Period own I/FU:I	łic	Company Rep	ort #97102901			
Outcome			PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other ORAL	Duratio	-	Thyroid Disorder	Health		Adderall	PS		ORAL
ORAL				Profess	₃ional				
Date:04/09/ Age:	98ISR Nur Gender:I		3153952-4Report Type:Period e I/FU:I	lic	Company Rep	ort #97111001			
Outcome Dose	Duratio		PT	Report	Source	Product	Role	Manufacturer	Route
Other 30 MG QD OR		-	Menometrorrhagia	Health		Adderall	PS		ORAL
20 MG QD CI	AL J	MOIN		Profess	sional				
	98ISR Nur Gender:I		3153954-8Report Type:Period e I/FU:I	lic	Company Rep	ort #97111702			
Outcome Dose	Duratio		PT	Report	Source	Product	Role	Manufacturer	Route
Other	Duració		Cerebrovascular Disorder Optic Neuritis	Health Profess		Adderall	PS		

Date:04/09/98ISR Number: 3153955-XReport Type:Periodic Company Report #97112101 Age:14 YR Gender:Male I/FU:I Company Report #97112101

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 10 MG PO	Duration	Mydriasis	Health	Adderall	PS		ORAL
10 1.0 1			Professional				
Date:04/09/9	81SR Number	: 3153957-3Report Type:Periodic	c Company Report	t #97112601			
Age:15 YR			-				Į
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalizat ORAL		Overdose	Health	Adderall	PS		ORAL
Initial or P Required Intervention	n to		Professional				
Prevent Perm Impairment/D							
	98ISR Number: Gender:Femal	: 3153959-7Report Type:Periodic le I/FU:I	c Company Report	t #97120101			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other 25 MG TID	3 MON	Alopecia	Consumer	Adderall	PS		

			FDA – Ad	lverse Event Reporting	System (AERS)	
			Free	edom Of Information (FO	I) Report	
Date:04/09/ Age:	/98ISR Number Gender:Unkn	: 3153960-3Report Type:Per own I/FU:I	riodic Company	Report #97120102		
Outcome	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Other		Leukopenia	Health Professional	Adderall	PS	
Date:04/09/ Age:	/98ISR Number Gender:Unkn	: 3153962-7Report Type:Per Lown I/FU:I	riodic Company	Report #97120103		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Other	Duration	Leukopenia	Health	Adderall	PS	ORAL
ORAL			Professional			
Date:04/09/ Age:40 YR	/98ISR Number Gender:Male	: 3153964-0Report Type:Per I/FU:I	riodic Company	Report #97120202		
Outcome	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Other	Duration	Urinary Retention	Consumer	Adderall 20	PS Shire Richwood	ORAL
30 MG ORAL	QD 6 WK			Flexaril	С	
				Klonopin	C	
				Ambien	С	
				Remeron	C	
Date:04/09/ Age:	/98ISR Number Gender:Unkn	: 3153966-4Report Type:Per own I/FU:I	ciodic Company	Report #97120301		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other ORAL	Duración	Thrombocytopenia	Health	Adderall	PS	ORAL
			Professional			

Date:04/09/98ISR Number Age: Gender:Male	r: 3153967-6Report Type:Periodi e I/FU:I	c Company Repor	t #97120501		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 20 MG ORAL QD 2 WK	Amblyopia	Consumer	Adderall	PS	ORAL
Date:04/09/98ISR Number Age: Gender:Unkn	r: 3153969-XReport Type:Periodi nown I/FU:I	c Company Repor	t #97121101		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 10 MG ORAL QD 2 WK	Convulsion	Health	Adderall	PS	ORAL
		Professional			
Date:04/09/98ISR Number Age: Gender:Unkn	r: 3153970-6Report Type:Periodi nown I/FU:I	c Company Repor	t #97120801		
Outcome Dose Duration	РТ	Report Source	Product	Role Manufacturer	Route
Other	Asthenia	Consumer	Adderall	PS	

			FDA – A	dverse Event Reporting	System (AERS)	
			Fre	edom Of Information (FO	I) Report	
	98ISR Number Gender:Male	r: 3153973-1Report Type:Per e I/FU:I	riodic Company	Report #97121201		
Outcome Dose	Duration	РТ	Report Source	Product	Role Manufacturer	Route
Other ORAL, 10 M	IG	Convulsion	Health Professional	Adderall 10	PS	ORAL
TID				Tegretol	С	
Date:04/09/ Age:	98ISR Number Gender:Male	r: 3154554-6Report Type:Per e I/FU:I	riodic Company	Report #97121202		
Outcome Dose Duration Disability 20 MG	Duration	PT	Report Source	Product	Role Manufacturer	Route
	Convulsion	Health	Adderall	PS		
Other			Professional	Depakote	С	
Date:04/09/ Age:11 YR	98ISR Number Gender:Male	r: 3154555-8Report Type:Per e I/FU:I	riodic Company	Report #97121203		
Outcome	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Other	Duration	Convulsion	Health	Adderall	PS	
20 MG	20 MG		Professional	Buspar Prozac	C C	
Date:04/09/ Age:9 YR	98ISR Number Gender:Fema	r: 3154557-1Report Type:Per ale I/FU:I	riodic Company	Report #98010801		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 15 MG QD	3 DAY	Confusional State	Health	Adderall	PS	ORAL
2.5 MG BID	12 WK	Gait Disturbance	Professional	Adderall	SS	

	8ISR Number Gender:Male	: 3154559-5Report Type:Periodic I/FU:I	c Company Repor	t #98011401			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other BID	2 MON	Electrocardiogram	Health	Adderall	PS		ORAL
		Abnormal	Professional	Clonidine	С		
Date:04/09/9 Age:11 YR		: 3154560-1Report Type:Periodio I/FU:I	c Company Repor	t #98012101			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 10 MG A.M.,	Duration	Neurosis	Consumer	Adderall	PS		
10 MG AFTER							
LUNCH	9 MON						
	8ISR Number Gender:Male	: 3154562-5Report Type:Periodio I/FU:I	c Company Repor	t #98012102			
Outcome	Dunction	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Priapism		Adderall Oral Tablets	PS		
20 mg qd	2 MON			Thioridazine And Haloperidol	С		

		FDA - Adverse	Event Reporting Syste	m (AER	S )	
		Freedom O:	f Information (FOI) Re	port		
8ISR Number: Gender:Male		c Company Repor	t #98012901			
	PT	Report Source	Product	Role	Manufacturer	Route
	Dermatitis	Health	Adderall	PS	Shire Richmond Inc.	ORAL
	Face Oedema	Professional				
T MON			Neosynephrine	SS		
8ISR Number: Gender:Male	: 3154566-2Report Type:Periodic I/FU:I	c Company Repor	t #98020501			
	PT	Report Source	Product	Role	Manufacturer	Route
	Drug Ineffective	Consumer	Adderall	PS		
8ISR Number: Gender:Male		c Company Repor	t #98020901			
	PT	Report Source	Product	Role	Manufacturer	Route
	Drug Ineffective	Consumer	Adderall	PS	Shire Richwood	ORAL
		c Company Repor	t #97102201			
	PT	Report Source	Product	Role	Manufacturer	Route
	Alopecia	Consumer	Adderall 5	PS		ORAL
	Gender:Male Duration 1 MON 8ISR Number: Gender:Male Duration 8ISR Number: Gender:Male Duration Y 4 MON 8ISR Number: Gender:Femal Duration	Gender:Male I/FU:I PT Duration PT Dermatitis Face Oedema 1 MON 8ISR Number: 3154566-2Report Type:Periodic Gender:Male I/FU:I PT Duration BISR Number: 3154568-6Report Type:Periodic Gender:Male I/FU:I PT Duration	BISE Number: 3154564-9Report Type:Periodic Company Repor Duration PT Report Source Dermatitis Health Face Oedema Professional 1 MON BISE Number: 3154566-2Report Type:Periodic Company Repor Gender:Male I/FU:I PT Report Source Drug Ineffective Consumer BISE Number: 3154568-6Report Type:Periodic Company Repor Gender:Male I/FU:I Duration PT Report Source Duration PT Report Source BISE Number: 3154568-6Report Type:Periodic Company Repor Gender:Male I/FU:I PT Report Source Duration PT Report Source BISE Number: 3157652-6Report Type:Periodic Company Repor Gender:Female I/FU:I PT Report Source BISE Number: 3157652-6Report Type:Periodic Company Repor Gender:Female I/FU:I PT Report Source PT Report Source	Freedom Of Information (FOI) Re         SISR Number: 3154564-9Report Type:Periodic       Company Report #98012901         Ouration       PT       Report Source       Product         Duration       PT       Report Source       Product         1       MON       Face Oedema       Professional       Neosynephrine         1       MON       FT       Report Source       Product         0       Duration       Iff0':I       Neosynephrine         8ISR Number:       3154566-2Report Type:Periodic       Company Report #98020501       Neosynephrine         0       Duration       PT       Report Source       Product         0       Durg Ineffective       Consumer       Adderall         RISR Number:       3154568-6Report Type:Periodic       Company Report #98020901         Gender:Male:       I/FU:I       PT       Report Source       Product         Duration       Prug Ineffective       Consumer       Adderall         Y       4       MON       Product       Moreau         8ISR Number:       3157652-6Report Type:Periodic       Company Report #97102201         Gender:Female       I/FU:I       PT       Report Source       Product         MON       PT       Rep	BISR Number:     3154564-9Report Type:Periodic     Company Report #98012901       PT     Report Source     Product     Role       Duration     PT     Report Source     Product     Role       1     MON     Face Oedema     Professional     Professional     S       1     MON     Face Oedema     Professional     Neosynephrine     SS       BISR Number:     3154566-2Report Type:Periodic     Company Report #98020501     SS       Gender::Male     I/FU'I     Company Report #98020501     Role       Duration     PT     Report Source     Product     Role       Duration     PT     Report Source     Product     Role       BISR Number:     3154568-5Report Type:Periodic     Company Report #98020501     SS       RISR Number:     3154568-5Report Type:Periodic     Company Report #98020901     SS       Duration     PT     Report Source     Product     Role       Duration     Drug Ineffective     Consumer     Adderall     PS       SISS Number:     3157652-6Report Type:Periodic     Company Report #97102201     SS       SISS Number:     3157652-6Report Type:Periodic     Company Report #97102201     SS       SISS Number:     3157652-6Report Type:Periodic     Company Report #97102201     SS <td>BISE Number: 3154564-9Report Type:Periodic Company Report 498012901 PT Report Source Product Role Manufacturer Duration Dermatitis Health Adderall PS Shire Richmond Inc. Face Oedema Professional 1 MON Neosynephrine SS BISE Number: 3154566-2Report Type:Periodic Company Report 498020501 BISE Number: 3154566-2Report Type:Periodic Company Report 498020501 Duration PT Report Source Product Role Manufacturer Duration PT Report Source Product Role Manufacturer Duration Drug Ineffective Consumer Adderall PS BISE Number: 3154568-6Report Type:Periodic Company Report 498020901 BISE Number: 3154568-6Report Type:Periodic Company Report 498020901 PT Report Source Product Role Manufacturer Duration Drug Ineffective Consumer Adderall PS Shire Richwood Y 4 MON</td>	BISE Number: 3154564-9Report Type:Periodic Company Report 498012901 PT Report Source Product Role Manufacturer Duration Dermatitis Health Adderall PS Shire Richmond Inc. Face Oedema Professional 1 MON Neosynephrine SS BISE Number: 3154566-2Report Type:Periodic Company Report 498020501 BISE Number: 3154566-2Report Type:Periodic Company Report 498020501 Duration PT Report Source Product Role Manufacturer Duration PT Report Source Product Role Manufacturer Duration Drug Ineffective Consumer Adderall PS BISE Number: 3154568-6Report Type:Periodic Company Report 498020901 BISE Number: 3154568-6Report Type:Periodic Company Report 498020901 PT Report Source Product Role Manufacturer Duration Drug Ineffective Consumer Adderall PS Shire Richwood Y 4 MON

Date:04/17/98ISR Number: 3074412-5Report Type:Expedited (15-DaCompany Report #98040901 Age:8 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
	Duration						
Other 10 MG SINGLE		Asthma	Health	Adderall	PS	Shire Richwood	
		Bronchospasm	Professional				
DOSE		Respiratory Distress					
	SISR Number: Gender:Male	: 3074415-0Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #97082701			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
	Duration		Health	Adderall	DC		0.0.0.1
Hospitalizati ORAL 10 MG	Lon –	Insomnia	Health	Adderall	PS		ORAL
Initial or Pr ONCE DAILY	rolonged 4 DAY	Respiratory Distress	Professional				
Other		Upper Respiratory Tract Infection					
	SISR Number: Gender:Male	: 3088237-8Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #98051201			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizati 5 MG	Duration lon -	Condition Aggravated	Health	Adderall	PS	Shire Richwood	ORAL
Initial or Pr		Dermatitis Iritis Pruritus Pyrexia Stevens-Johnson Syndrome Tongue Disorder	Professional				

Freedom Of Information (FOI) Report

Date:06/01/98ISR Number: 3088241-XReport Type:Expedited (15-DaCompany Report #98051501 Age:8 YR Gender:Male I/FU:I

					,
PT	Report Source	Product	Role	Manufacturer	Route
Convulsion	Health	Adderall	PS	Shire Richwood	ORAL
Hepatic Enzyme Increased	Professional	Depakote	SS		
Hepatic Function Abnormal		Depakote Over The Counter	С		
Malaise Vomiting		Triaminic	С		
	ed (15-DaCompany Repor	t #98051201			
	_	<b>-</b> .	- 7		
PT	Report Source	Product	Ro⊥e	Manufacturer	Route
Conjunctivitis	Health	Adderall	PS	Shire Richwood	ORAL
Dermatitis	Professional				
Oral Mucosal Eruption Pruritus Stevens-Johnson Syndrome					
Stevens-compon synarome					
: 3098706-2Report Type:Direct I/FU:I	Company Report	t #			
PT	Report Source	Product	Role	Manufacturer	Route
Convulsion		Adderall	PS		ORAL
		Robitussin	SS		ORAL
	Convulsion Hepatic Enzyme Increased Hepatic Function Abnormal Hepatocellular Damage Malaise Vomiting 3091144-8Report Type:Expedite I/FU:F PT Conjunctivitis Dermatitis Oral Mucosal Eruption Pruritus Stevens-Johnson Syndrome 3098706-2Report Type:Direct I/FU:I PT	Convulsion Health Hepatic Enzyme Increased Professional Hepatic Function Abnormal Hepatocellular Damage Malaise Vomiting 3091144-8Report Type:Expedited (15-DaCompany Report I/FU:F PT Report Source Conjunctivitis Health Dermatitis Professional Oral Mucosal Eruption Pruritus Stevens-Johnson Syndrome 3098706-2Report Type:Direct Company Report I/FU:I PT Report Source	ConvulsionHealthAdderallHepatic Enzyme IncreasedProfessionalDepakoteHepatic Function Abnormal Hepatocellular Damage Malaise YomitingDepakote Over The Counter TriaminicS091144-8Report Type:Expedited (15-DaCompany Report I/FU:FProductPTReport SourceProductConjunctivitisHealthAdderallDermatitisProfessionalCompany ReportOral Mucosal Eruption Pruritus Stevens-Johnson SyndromeCompany Report +TReport SourceProductPTReport SourceAdderallOral Mucosal Eruption Pruritus Stevens-Johnson SyndromeCompany Report +TReport SourceProductOnyulsionKaport SourceAdderallPTReport SourceProductConvulsionKaport SourceAdderall	Convulsion Health Adderall PS Hepatic Enzyme Increased Professional Depakote SS Hepatic Function Abnormal Hepatocellular Damage Malaise Vomiting Report Type:Expedit (15-DaCompany Report Triaminic C 3091144-8Report Type:Expedit (15-DaCompany Report #98051201 I/FU:F PT Report Source Product Role Conjunctivitis Health Adderall PS Dermatitis Professional Oral Mucosal Eruption Pruritus Stevens-Johnson Syndrome 3098706-2Report Type:Direct Company Report # T/FU:I PT Report Source Product Role Convulsion Syndrome PT Report Source Product Role Company Report # PS Professional PS Professional Professional PS Professional Pruritus PS Profuct PS Product Role PT Report Source Product Role PT Report Source Product PS	Convulsion Health Adderall FS Shire Richwood Hepatic Enzyme Increased Professional Depakote SS Hepatic Function Abhormal Hepatocellular Damage Malaise Vomiting Report Dacompany Revert He Counter Triaminic C 3091144-8Report Type:Expeditor IS-Dacompany Revert H98051201 I/FU:F PT Report Source Product Role Manufacturer Conjunctivitis Health Adderall PS Shire Richwood Dermatitis Professional Oral Mucosal Eruption Pruritus Stevens-Johnson Syndrome Stevens-Johnson Syndrome Stevens-Johnson Syndrome T Report Source Product Role Manufacturer PT Report Source Product Role Manufacturer

Report Source Product Role Manu Adderall 10 PS Depakote SS Zyprexa SS	ufacturer Route
Depakote SS	
l (15-DaCompany Report #US9834-ADD	
eport Source Product Role Manu	ufacturer Route
	re Richwood ORAL
lepo: leal	rt Source Product Role Man

Freedom Of Information (FOI) Report

Date:09/04/98ISR Number: 3126263-0Report Type:Expedited (15-DaCompany Report #98USA11254 Age:17 YR Gender:Female I/FU:I

							,
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizati 10 MG TID	Duration ion -	Aggression	Health	Ritalin	PS		ORAL
IN MG TID Initial or Pr ORAL	colonged	Emotional Disorder	Professional				
		Psychotic Disorder		Adderall 20	SS		ORAL
60 MG DAILY							<b>!</b>
ORAL							l
Date:09/08/98 Age:18 YR G		: 3127022-5Report Type:Expedite	ed (15-DaCompany Repor	t #US9837-ADD			
Age. 10 IN C	Jenuer • Marc	1/ - 0 - 1					!
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
	ose Duration ospitalization -	Cold Sweat	Health	Adderall	PS	Shire Richwood	ORAL
Initial or Pr 10 MG PM	colonged	Feeling Cold	Professional				
(	2 DAX	Heat Exposure Injury					I
(ORALLY)	2 DAY	Tremor					
Data:10/07/98	ATCD Number	: 3290794-3Report Type:Periodic	c Company Report	+ #TTC0255			
	Gender:Male			- #057033			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 20MG AM, 10MG		Convulsion	Consumer	Adderall	PS		
NOON				Nortriptyline	С		

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - 4 DAY	Bronchitis		Adderall	PS	Shire Richwood	
	Dehydration Eye Disorder Mucosa Vesicle Oral Intake Reduced Oral Soft Tissue Disorder Pyrexia Rash Vesicular Stevens-Johnson Syndrome Urinary Retention Vomiting 3162514-4Report Type:Expedit I/FU:F	ed (15-DaCompany Repor	Zithromax Prednisone t #US9852	SS C		
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Life-Threatening 1 WK	Eye Disorder	Health	Adderall	PS	Shire Richwood	
	Oral Mucosal Eruption	Professional	Zithromax	SS		
Initial or Prolonged	Rash Vesicular Stevens-Johnson Syndrome		Prednisone Zithromax	C C		

Date:11/25/98ISR Number: 3163288-3Report Type:Expedited (15-DaCompany Report #US9853 Age:8 YR Gender:Male I/FU:F

Outcome Hospitalization -Initial or Prolonged

Freedom Of Information (FOI) Report

Other

							,
Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Activated Partial	Health	Adderall	PS		ORAL
5MG ORALLY Ç		Thromboplastin Time	Professional	Depakote	SS		ļ
UNKNOWN	UNKNOW	N Prolonged Hepatic Enzyme Increased Hepatocellular Damage Liver Function Test Abnormal Malaise Prothrombin Time Prolonged Vomiting		Triaminic	С		
	99ISR Number Gender:Male	r: 3184754-0Report Type:Direct e I/FU:I	Company Repor	't #			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 1 TAB 20 MG	Duration	Arthralgia		Adderall 20	PS	Richwood	ORAL
AM		Joint Swelling					
FM-1				Pamelor	С		
	99ISR Number Gender:Male	r: 3300077-0Report Type:Periodio e I/FU:I	ic Company Repor	t #M086449			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose		Mania	Consumer	Serzone Tabs 200 Mg	PS		ORAL
200-100 MG H	hs 2 wk	Tachycardia		Adderall Wellbutrin	SS C		
4							,

Outcome Dose I	Duration	PT	Report Source	Product	Role	Manufacturer	Route
10 MG, TID,	2	Aggression Emotional Disorder Psychotic Disorder	Health Professional	Ritalin Tablet 10 Mg (Methylphenidate Hydrochloride)	PS		ORAL
ORAL				Adderall Tablet 20			
60 MG,DAILY,				Mg (Adderall)	SS		ORAL

Date:02/10/99ISR Number: 3195485-5Report Type:Expedited (15-DaCompany Report #US9908900 Age:9 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - DAILY	Arthralgia	Health	Adderall	PS	
Initial or Prolonged	Neutropenia Pyrexia Sepsis	Professional	Albuterol Nebulizations Oxacillin Clindamycin	C C C	

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ORAL

Age:62 YR Ger Dutcome	nder:Male uration	: 3195487-9Report Type:Expe I/FU:I PT Hypertension Myocardial Infarction		om Of Information (FOI) Re eport #US9908800 Product			
Age:62 YR Ger Dutcome Dose Du Death 10 MG AM; 5	nder:Male uration	I/FU:I PT Hypertension	Report Source		Role		
Dose Du Death 10 MG AM; 5	uration	Hypertension		Product	Role		
Death 10 MG AM; 5			Health		Role Manufacturer		Route
		Myocardial Infarction		Adderall	PS		
			Professional				
Date:02/22/9915 Age:56 YR Ger		: 3205535-5Report Type:Peri le I/FU:I	odic Company Re	eport #8-98365-079A			
Dutcome		PT	Report Source	Product	Role	Manufacturer	Route
ose Duration ther 5 MG THREE	Diarrhoea	Consumer	Effexor Xr Capsules	PS		ORAL	
	Dyspepsia						
TIMES DAILY DRAL		Nausea					
				Adderall (Dextroamphetamine/ Amphetamine Mixture) Tablets	SS		ORAL
ORAL				Seroquel (Quetiapine) Tablets	SS		ORAL
ORAL				Xanax	C		
	SR Number: nder:Femal	: 3395745-9Report Type:Peri le I/FU:I	odic Company Re	eport #WAES 98091423			
Dutcome	uration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Di		Dry Mouth Dysphonia Tongue Disorder	Health Professional	Tab Zocor Unk Inhl Pulmicort Turbuhaler 400	PS		
RESPIRATORY				Microgm	SS		
(INHALATION)	400						

MICROGM/BID/I	
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NH		Atrovent 6 Puff	
RESPIRATORY		(Unit)	SS
(INHALATION)	6 PUFF		
(UNIT)/Q4H/IN			
H		Ventolin 4 Puff (Unit)	SS
RESPIRATORY			66
(INHALATION)	4 PUFF		
(UNIT)/Q4H/IN			
H			
		Tussionex Unk	SS
		Prilosec Unk	SS
		Norvasc Unk	SS
		Zoloft Unk Adderall Tablets Unk	SS SS
		Augmentin Unk	SS
		Prednisone Unk	SS
	Number: 3208360-4Report Type:Periodic Co er:Male I/FU:F	mpany Report #9725281	

Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 50.00 MG	Duracion	Asthenia	Consumer	Zoloft Tablets	PS	ORAL
		Drug Interaction	Health			
TOTAL: DAILY		Malaise	Professional			
ORAL		Neurosis		Adderall	SS	ORAL
ORAL						

				FDA	- Adverse	Event Reporting Sys	stem (AER	LS)	
				:	Freedom Oi	Information (FOI)	Report		
	9ISR Number Gender:Fema	: 3217086-2Report le I/FU:I	Type:Periodic	Comp	any Report	#9812056			
Outcome Dose	Duration	PT		Report Source	e	Product	Role	Manufacturer	Route
Other 25 MG TOTAL	Duración	Drug Interaction		Health		Zoloft Tablets	PS		ORAL
DAILY ORAL		Ecchymosis		Professional					
30 MG TOTAL						Adderall 10	SS		ORAL
TID ORAL									
Date:03/02/9 Age:50 YR ( Outcome		: 3440747-7Report le I/FU:I PT		Compa Report Source		#MPI-982200 Product	Role	Manufacturer	Route
Dose	Duration	Drug Interaction		Health	C	Tussionex	PS	Medeva	
		Dry Mouth Dysphonia		Professional		Pulmicort Turbuhale		Pharmaceuticals Inc	
RESPIRATORY		Glossitis							
(INHALATION)	400 MC	G BID, Tongue Disorder							
INH		Tongue Oedema				Atrovent	SS		
RESPIRATORY	6 PUFF:	c Odu							
INH	0 1011.	, y,							
RESPIRATORY						Ventolin	SS		
(INHALATION)	4 PUFF:	5 Q4H,							
INH									
						Prilosec Norvasc Zoloft Adderall	SS SS SS SS		
						Zocor Augmentin	SS SS		

				Prednisone	SS		
	99ISR Number: Gender:Male	: 3230038-1Report Type:Periodi I/FU:I	.c Company Repo	rt #US98001			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 20 MG	Duracton	Emotional Disorder	Health	Adderall	PS		
		Hostility Psychotic Disorder	Professional	Paxel Tenex	C C		
	99ISR Number: Gender:Male	: 3230041-1Report Type:Periodi I/FU:I	c Company Repo	rt #US98002			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 15 MG	DULACION	Rash Maculo-Papular	Health	Adderall	PS		
			Professional				
	99ISR Number: Gender:Male	: 3230043-5Report Type:Periodi I/FU:I	C Company Repo	rt #US98003			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10 MG BID	Duración	Haematuria	Health	Adderall	PS		
		Nephrolithiasis	Professional				

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report							2S)	
Date:03/30/ Age:7 YR	99ISR Number Gender:Fema	: 3230045-9Report Type:Period le I/FU:I	lic	Company Repo	rt #US98004			
Outcome Dose	Duration	PT	Report	Source	Product		Manufacturer	Route
Other DAILY - 20 PO QD	MG	Hallucination	Health Profess	ional	Adderall	PS		ORAL
Date:03/30/ Age:8 YR	99ISR Number Gender:Male	: 3230046-0Report Type:Period I/FU:I	lic	Company Repo	rt #US98005			
Outcome Dose Durati Other 10MG AM, 5MG	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
		Dizziness	Consume	r	Adderall	PS		
AFTNOON		Hyperhidrosis Pallor			Dapakote	С		
	99ISR Number Gender:Male	: 3230047-2Report Type:Period I/FU:I	lic	Company Repo:	rt #US98007			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other DAILY	Duración	Vomiting	Consume	r	Adderall	PS		
Date:03/30/ Age:15 YR	99ISR Number Gender:Male	: 3230048-4Report Type:Period I/FU:I	lic	Company Repo	rt #US98008			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other 60MG EACH	Duración	Anorexia	Consume	r	Adderall	PS		
MORNING		Gilbert'S Syndrome Hyperbilirubinaemia Jaundice						

	99ISR Number Gender:Male	: 3230050-2Report Type:Period I/FU:I	ic Company Repo	rt #US98010		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other DAILY	Duración	Hyperglycaemia	Consumer	Adderall	PS	
DAIDI				Insulin	C	
	/99ISR Number Gender:Fema	: 3230052-6Report Type:Period le I/FU:I	ic Company Repo	rt #US98011		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other 10MG AM+ 5M	Duration 1G	Asthenia	Other	Adderall	PS	
NO.0N		Chest Pain				
NOON				Prozac	C	
Date:03/30, Age:9 YR	/99ISR Number Gender:Male	: 3230054-XReport Type:Period I/FU:I	ic Company Repo	rt #US98013		
Outcome		РТ	Report Source	Product	Role Manufacturer	Route
Dose Other 10MG MORNIN	Duration	Anorexia	Consumer	Adderall	PS	
5 MG		Nervousness		Dextrostat	SS	

AFTERNOON

						(		
					e Event Reporting Syst		LS )	
				Freedom C	Of Information (FOI) F	leport		
	99ISR Number Gender:Male	: 3230055-1Report Type:Perio I/FU:I	dic	Company Repor	rt #US98014			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other 20MG DAILY	Duración	Convulsion	Health		Adderall	PS		
		Paraesthesia	Profess	ional				
	99ISR Number Gender:Male	: 3230057-5Report Type:Perio I/FU:I	dic	Company Repor	ct #US98015			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other 20MG PO QI		Blood Alkaline	Health		Adderall	PS		ORAL
20149 10 2.	5	Phosphatase Increased Hypertension	Profess	ional				
Date:03/30/9 Age:7 YR	99ISR Number: Gender:	: 3230058-7Report Type:Perio I/FU:I	dic	Company Repor	ct #US98016			
Outcome	Direction	РТ	Report	Source	Product	Role	Manufacturer	Route
Dose Other 10MC DO OD	Duration	Muscle Twitching	Study		Adderall	PS		ORAL
10MG PO QD		Tic	Health Profess	ional				
Date:03/30/9 Age:10 YR	99ISR Number Gender:Male	: 3230060-5Report Type:Perio I/FU:I	dic	Company Repor	ct #US98017			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other 10MG PO DAII		Hallucination	Health		Adderall	PS		ORAL
TOMG FO DAT	ΤŢ		Profess	ional	Hiv Combinations Pentamadine	С		
					Nebulizations	C		
					Azithromycin	С		

	99ISR Number: Gender:Male	3230062-9Report Type:Periodi I/FU:I	c Company Repor	t #US98018					
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route			
Other 10 MG DAILY		Insomnia	Consumer	Adderall	PS				
		Sleep Disorder Weight Decreased	-						
	99ISR Number: Gender:Femal	3230063-0Report Type:Periodi e I/FU:I	c Company Repor	t #US98020					
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route			
Other 5MG PO BID	Duración	Rash Maculo-Papular	Health	Adderall	PS	ORAL			
SWG FO DID			Professional						
Date:03/30/ Age:18 YR	99ISR Number: Gender:Male	3230067-8Report Type:Periodi I/FU:I	c Company Repor	t #US98023					
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route			
Other BID		Neurosis	Health	Adderall	PS				
20MG QOD		Weight Decreased	Professional	Prozac	SS				

					Event Reporting System f Information (FOI) Rep		S)	
	9ISR Number: Gender:Femal	: 3230068-XReport Type:Periodic le I/FU:I	2	Company Report	: #US98024			
Outcome	<b>D</b>	PT	Report S	Source	Product	Role	Manufacturer	Route
Dose Other 10MG	Duration 5 DAY	Hypersensitivity	Health		Adderall	PS		
			Professi	.onal				
	9ISR Number: Gender:Male	: 3230069-1Report Type:Periodic I/FU:I	C	Company Report	: #US98025			
Outcome Dose Duration Other	Duration	PT	Report S	Jource	Product	Role	Manufacturer	Route
	Duration	Constipation	Health		Adderall	PS		
7.5MG AM+2.5MG NOOI	NT		Professi	lonal				
AMTZ. JHG NOO	N .							
	9ISR Number: Gender:Male	: 3230080-0Report Type:Periodic I/FU:I	2	Company Report	: #US98026			
Outcome Dose	Duration	PT	Report S	Source	Product	Role	Manufacturer	Route
Other	Duration	Personality Disorder	Health		Adderall	PS		ORAL
10-20 MG PO			Professi	lonal				
QD					Luvox	С		
	9ISR Number: Gender:Male	: 3230083-6Report Type:Periodic I/FU:I	2	Company Report	: #US98027			
Outcome	Duration	PT	Report S	Source	Product	Role	Manufacturer	Route
Other		Syncope	Study		Adderall	PS		ORAL
2.5 MG PO AM			Health Professi	ional				

	99ISR Number Gender:Male	r: 3230086-1Report Type:Perio e I/FU:I	dic Company Re	port #US98028		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 10 MG BID	5 WK	Abnormal Behaviour	Study	Adderall	PS	
		Personality Disorder	Health Professional			
	99ISR Number Gender:Male	r: 3230088-5Report Type:Perio e I/FU:I	dic Company Re	port #US98029		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other BID	7 DAY	Anxiety	Health	Adderall	PS	
	, Din		Professional	Minocycline Valtrex	C C	
Date:03/30/9 Age:15 YR		r: 3230090-3Report Type:Perio ale I/FU:I	dic Company Re	port #US98031		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalizat 10 MG PO BII		Anxiety	Health	Adderall	PS	ORAL
Initial or H Other		•	Professional			

		FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report							
	9ISR Number Gender:Fema	: 3230092-7Report Ty le I/FU:I	pe:Periodic	Company R	eport #US98032				
Outcome Dose Other BID	Duration	PT	Report	Source	Product	Role	Manufacturer	Route	
		Deafness	Health		Adderall	PS			
		Dizziness Nausea Tinnitus	Profes	sional	Nortripityline	С			
	9ISR Number Gender:Fema	: 3230095-2Report Ty le I/FU:I	pe:Periodic	Company R	eport #US98033				
Outcome	Duration	PT	Report	Source	Product	Role	Manufacturer	Route	
Dose Other 20 MG PO		Tremor	Health		Adderall	PS		ORAL	
DAILY			Profes	sional					
	9ISR Number Gender:Male	: 3230097-6Report Ty I/FU:I	pe:Periodic	Company R	eport #US98035				
Outcome	Duration	PT	Report	Source	Product	Role	Manufacturer	Route	
Dose Other		Dystonia	Health		Adderall	PS			
BID			Profes	sional	Catapres Respirisdol	C C			
					Hyddrocortisone Cream	С			
	9ISR Number Gender:Fema	: 3230099-XReport Ty le I/FU:I	pe:Periodic	Company R	eport #US98036				
Outcome Dose Other 30 MG DAILY	Duration 11 MON	PT	Report	Source	Product	Role	Manufacturer	Route	
		Depression	Consum	er	Adderall	PS			

Date:03/30/99 Age:64 YR G		3230102-7Report Type:Periodic .e I/FU:I	Company Report	t #US98038		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 10 MG AM 5MG		Dysuria	Consumer	Adderall	PS	
PM	4 MON	Urinary Retention				
7.5 MG IN PM				Dexedrine	SS	
Age:7 YR G Outcome	Sender:Male		Report Source	t #US98039 Product Adderall		Route ORAL
	ISR Number: Gender:Male	3230107-6Report Type:Periodic I/FU:I	c Company Report	t #US98040		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other 10 MG AM, 10	Duration	Hostility	Consumer	Adderall	PS	
MG PM	2 YR			Ddavp	С	

				FDA - Adverse	e Event Reporting Syste	m (AER	S)	
				Freedom O	of Information (FOI) Re	port		
	9ISR Number Gender:Male	: 3230109-XReport Type:Periodi I/FU:I	lc	Company Repor	t #US98041			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other 15 MG PO BID		Dermatitis Exfoliative	Health		Adderall	PS		ORAL
		Eczema	Profess	sional	Clonodine Lithium Wellbutrin Ceclor	C C C C		
	9ISR Number Gender:Male	: 3230111-8Report Type:Periodi I/FU:I	lc	Company Repor	t #US98042			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other 10 MG AM AND		Abnormal Dreams	Consume	er	Adderall	PS		
NOON								
Date:03/30/9 Age:52 YR		: 3230113-1Report Type:Periodi I/FU:I	ic	Company Repor	t #US98043			
Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Testicular Atrophy	Consume	er	Adderall	PS		
60 MG DAILY		Testicular Failure	Health Profess					
	9ISR Number Gender:Male	: 3230116-7Report Type:Periodi I/FU:I	ic	Company Repor	t #US98044			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other 15 MG BID	Duración	Muscle Twitching	Consume	ər	Adderall	PS		

	99ISR Number Gender:Male	: 3230118-0Report Type:Periodi I/FU:I	.c Company Repor	t #US98045			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 25 MG DAILY	Duración	Alopecia	Consumer	Adderall	PS		
	99ISR Number Gender:Fema	: 3230120-9Report Type:Periodi le I/FU:I	.c Company Repor	t #US98046			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 50 MG DAILY	Daración	Anxiety	Consumer	Adderall	PS		
		Psychotic Disorder		Albuterol Inha Depakote Klonopin Paxel	SS C C C		
	99ISR Number Gender:Male	: 3230121-0Report Type:Periodi I/FU:I	.c Company Repor	t #US98047			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 20 MG BID		Aggression	Consumer	Adderall	PS		
400 MG BID		Drug Effect Increased		Cimetidine	SS		

			ר ג תים	dverse Event Reporting Sy	AFPS)	
			Fre	edom Of Information (FOI)	Report	
	9ISR Number Gender:Male	: 3230122-2Report Type:Peric I/FU:I	odic Company	Report #US98048		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 10 MG BID		Petit Mal Epilepsy	Consumer	Adderall	PS	
10 MG TWICE				Dextrostat	SS	
DAILY						
	9ISR Number Gender:Fema	: 3230123-4Report Type:Peric le I/FU:I	odic Company	Report #US98050		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 15 MG AM 10	Duración	Chest Pain	Consumer	Adderall	PS	
MG PM				Surson	С	
	9ISR Number Gender:Male	: 3230124-6Report Type:Peric I/FU:I	odic Company	Report #US98051		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 5 MG ORALLY	Duración	Dermatitis		Adderall	PS	ORAL
BID		Urticaria				
				Benadryl	SS	
	9ISR Number Gender:Male	: 3230125-8Report Type:Peric I/FU:I	odic Company	Report #US98054		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 20 MG PO Q A		Syncope	Health	Adderall	PS	ORAL

			Professional	Zoloft	С	
Date:03/30/9 Age:6 YR	99ISR Number: Gender:Male	: 3230126-XReport Type:Periodi I/FU:I	ic Company Report	t #US98056		
Outcome	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Other		Hallucination	Health	Adderall	PS	ORAL
10 MG PO BII	)		Professional			
Date:03/30/9 Age:6 YR	99ISR Number: Gender:Male	: 3230127-1Report Type:Periodi I/FU:I	ic Company Report	t #US98057		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other 20 MG AM 10		Deafness	Consumer	Adderall	PS	
MG PM				Doxepin	SS	
	99ISR Number: Gender:Male	: 3230128-3Report Type:Periodi I/FU:I	ic Company Report	t #US98058		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 45-60 MG PO		Hypertension	Health	Adderall	PS	ORAL
DAILY			Professional			
DAILI				Paxel	С	
4						

			FDA - Adverse	e Event Reporting Syste	em (AERS)	
			Freedom (	Df Information (FOI) Re	eport	
	99ISR Number Gender:Fema	: 3230129-5Report Type:Periodi le I/FU:I	.c Company Repoi	rt #US98059		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 10 MG BID	2 42 4 7 2 6 1	Headache	Consumer	Adderall	PS	
		Papilloedema		Lasix	С	
	91SR Number Gender:Male	: 3230130-1Report Type:Periodi I/FU:I	.c Company Repo	rt #US98061		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 20 MG AM 10	Duración	Vasodilatation	Health	Adderall	PS	
NOON			Professional			
Date:03/30/9 Age:35 YR		: 3230131-3Report Type:Periodi le I/FU:I	.c Company Repo	rt #US98062		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other	Duration	Vasodilatation	Health	Adderall	PS	
10 mg am ane noon	)	Vasospasm	Professional			
	991SR Number Gender:Fema	: 3230132-5Report Type:Periodi le I/FU:I	.c Company Repoi	rt #US98063		
Outcome Dose	Duration	РТ	Report Source	Product	Role Manufacturer	Route
Dose Other 20 MG BID	DULALION	Hypertension	Health	Adderall	PS	
AN MG RID		Muscle Twitching Palpitations	Professional	Prilosec	С	

Date:03/30/9 Age:7 YR	99ISR Number: Gender:Male	: 3230133-7Report Type:Per I/FU:I	iodic Company	Report #US98064		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 5 MG DAILY		Muscle Twitching	Health	Adderall	PS	
			Professional			
Date:03/30/9 Age:14 YR	99ISR Number: Gender:Male	: 3230134-9Report Type:Per I/FU:I	iodic Company	Report #US98065		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 20 MG		Agitation	Health	Adderall	PS	
20 199			Professional	Paxel	С	
Date:03/30/9 Age:17 YR	99ISR Number: Gender:Male	: 3230135-0Report Type:Per I/FU:I	iodic Company	Report #US98066		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other		Overdose	Health Professional	Adderall	PS	

			FDA - Adverse	e Event Reporting System	em (AERS)	
			Freedom O	Of Information (FOI) Rej	port	
	9ISR Number: Gender:Male	: 3230137-4Report Type:Periodic I/FU:I	c Company Repor	t #US98067		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other	Duration	Central Nervous System	Consumer	Adderall	PS	I
5 MG AM & PM		Stimulation				
	9ISR Number: Gender:Male	: 3230138-6Report Type:Periodic I/FU:I	c Company Repor	't #US98068		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other 30 MG	Duration	Eye Rolling	Health	Adderall	PS	
		Muscle Twitching	Professional			
	9ISR Number: Gender:Femal	: 3230140-4Report Type:Periodic le I/FU:I	c Company Repor	t #US98069		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other		Visual Disturbance	Consumer	Adderall	PS	ORAL
80 mg oral Qi	D			Timoptic Alphagan Trusopt	С С С	
	9ISR Number: Gender:Femal	: 3230144-1Report Type:Periodic le I/FU:I	c Company Repor	't #US98070		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other	Duration	Purpura	Health	Adderall	PS	
20 MG BID			Professional	Synthroid	С	

	99ISR Number: Gender:Male	: 3230146-5Report Type:Period I/FU:I	dic Company Repor	t #US98071			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Pyrexia	Health Professional	Adderall Parnate Lithium	PS C		
	99ISR Number: Gender:Femal	: 3230148-9Report Type:Period le I/FU:I	dic Company Repor	rt #US98072			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other 5 MG ONCE		Diarrhoea	Consumer	Adderall	PS		
DAILY				Seroquil Estrace	C C		
	99ISR Number: Gender:Male	: 3230150-7Report Type:Period I/FU:I	dic Company Repor	rt #US98075			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other 10 MG QD PO		Urticaria	Health	Adderall	PS		ORAL
			Professional				

						FDA – Adve	erse E	vent Reporting Sys	stem (AER	S)	
						Freedo	om Of	Information (FOI)	Report		
	991SR Number Gender:Fema		95-7Report Tyj I/FU:I	pe:Periodic	2	Company Re	eport	#US98076			
Outcome Dose	Duration	PT			Report	Source	F	roduct	Role	Manufacturer	Route
Other 20 MG DAILY		Urtica	ria		Consume	er	A	dderall	PS		ORAL
PO							Г	egretol	С		
	99ISR Number Gender:Male		96-9Report Tyj I/FU:I	pe:Periodic	2	Company Re	eport	#US98077			
Outcome Dose	Duration	PT			Report	Source	F	roduct	Role	Manufacturer	Route
Other 5 MG BID		Chest	Pain		Consume	er	A	dderall	PS		
								enuate Immediate elease	С		
	91SR Number Gender:Fema		97-0Report Ty I/FU:I	pe:Periodic	C	Company Re	eport	#US98079			
Outcome Dose	Duration	PT			Report	Source	F	roduct	Role	Manufacturer	Route
Other MISSIG DATA	Duración	Stomat	itis		Health		A	dderall	PS		
					Profes	sional	Т	egretol	С		
	99ISR Number Gender:Male		98-2Report Tyj I/FU:I	pe:Periodic	2	Company Re	eport	#US98080			
Outcome Dose	Duration	PT			Report	Source	F	roduct	Role	Manufacturer	Route
Other 10-30 MG	Duration C	Cough			Consume	er	A	dderall	PS		
DAILY		Muscle	Twitching								
		Tic									

SR Number: nder:Male	3230199-4Report Type:Periodic I/FU:I	Company Report	t #US98081		
uration	PT	Report Source	Product	Role Manufacturer	Route
	Neurosis	Health	Adderall	PS	
		Professional			
		Company Repor	t #US98082		
	PT	Report Source	Product	Role Manufacturer	Route
	Purpura	Health	Adderall	PS	ORAL
		Professional			
SR Number: nder:Male	3230201-XReport Type:Periodic I/FU:I	c Company Repor	t #US99083		
	PT	Report Source	Product	Role Manufacturer	Route
	Hyperglycaemia	Health	Adderall	PS	
		Professional	Insulin	SS	
	nder:Male uration SR Number: nder:Femal uration SR Number: nder:Male uration	nder:Male I/FU:I PT uration Neurosis Obsessive-Compulsive Disorder SR Number: 3230200-8Report Type:Periodic nder:Female I/FU:I PT uration PUrpura SR Number: 3230201-XReport Type:Periodic nder:Male I/FU:I PT	nder:Male I/FU:I Report Source uration PT Report Source Neurosis Health Obsessive-Compulsive Professional Disorder Company Report SR Number: 3230200-8Report Type:Periodic Company Repor nder:Female I/FU:I PT Report Source uration Purpura Health Professional SR Number: 3230201-XReport Type:Periodic Company Repor nder:Male I/FU:I Company Repor Purpura Health Professional Health	nder:Male I/FU:I PT Report Source Product Neurosis Health Adderall Obsessive-Compulsive Professional Disorder Obsessive-Compulsive Company Report #US98082 nder:Female I/FU:I PT Report Source Product Purpura Health Adderall Professional SR Number: 3230201-XReport Type:Periodic Company Report #US99083 I/FU:I PT Report Source Product Purpura Health Adderall Professional PT Report Source Product Hyperglycaemia Health Adderall	nder:Male I/FU:I TFU:I PT Report Source Product Role Manufacturer Neurosis Health Adderall PS Obsessive-Compulsive Professional Disorder Obsessive-Compulsive Company Report #US98082 SR Number: 3230200-8Report Type:Periodic Company Report #US98082 Ther:Female T/FU:I PT Report Source Product Role Manufacturer Purpura Health Adderall PS Professional SR Number: 3230201-XReport Type:Periodic Company Report #US99083 SR Number: 1/FU:I SR Number: 3230201-XReport Type:Periodic Company Report #US99083 SR Number: 1/FU:I S

			FDA – Ad	lverse Event Reporting Sys	stem (AERS)	
				edom Of Information (FOI)		
	Gender:Male	: 3230202-1Report Type:Pe I/FU:I	riodic Company	Report #US99084		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 5 MG TID QID	)	Thyroid Disorder	Health	Adderall	PS	
250 MCG DAIL	ΥY		Professional	Synthroid (Flint	SS	
				Flomax	C	
				Vanconase Spray	C	
				Nasalcrom	С	
				Entes	С	
				Ginko	С	
				Prilosec	С	
	9ISR Number Gender:Male	: 3230203-3Report Type:Pe I/FU:I	riodic Company	Report #US99085		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other 5 MG DAILY	Duration	Dermatitis	Consumer	Adderall	PS	
J MG DAILI				Depakote	C	
Date:03/30/9	9ISR Number	: 3230204-5Report Type:Pe	riodic Company	Report #US99086		
	Gender:Fema			-		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other		Drug Abuser Drug Dependence	Health Professional	Adderall	PS	
	9ISR Number Gender:Male	: 3230205-7Report Type:Pe I/FU:I	riodic Company	Report #US99087		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 10 MG AM AND		Alopecia	Consumer	Adderall	PS	

	9ISR Number: Gender:Male	: 3230206-9Report Type:Period I/FU:I	lic Company Repor	rt #US99090			
Outcome	5	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 5 MG PO AM &	Duration	Alopecia	Consumer	Adderall	PS		
AFTERNOON							
	9ISR Number: Gender:Male	: 3230918-7Report Type:Expedi I/FU:F	ted (15-DaCompany Repor	rt #US9805501			
Outcome	Dunction	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 20 MG AM,	Duration	Convulsion		Adderall	PS		
10mg noon				Nortriptyline	С		
	9ISR Number: Gender:Male	: 3231057-1Report Type:Expedi I/FU:I	ted (15-DaCompany Repor	rt #US99095			
Outcome Other		PT Attention Deficit/Hyperactivity Disorder					
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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Dose	Duration	Condition Aggravated Convulsion	Report Source	Product		Manufacturer	Route
5 MG TID			Health	Adderall	PS		
			Professional	Clonidine	С		
Date:04/02/ Age:9 YR	99ISR Number Gender:Fema	: 3232128-6Report Type:Expedi- le I/FU:F	ted (15-DaCompany Repo:	rt #US99089			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitaliza 15 MG PO		Arthralgia	Health	Adderall	PS		
Initial or DAILY	Prolonged	Arthritis Bacterial	Professional				
		Neutropenia Pyrexia		Albuterol Oxacillin Clindamycin	С С С		
Age:9 YR Dutcome	Gender:Fema	: 3257612-0Report Type:Direct le I/FU:I PT	Company Repo: Report Source	rt # Product	Role	Manufacturer	Route
Dose	Duration	Dyskinesia	Health	Adderall Tab Rexar	PS	Rexar	ORAL
7.5MG AM & NOON PO	20 day	Restlessness	Professional	Buspar Thorazine Benadryl Inj	C C C		
Date:05/17/ Age:6 YR	99ISR Number Gender:	: 3266261-XReport Type:Period I/FU:I	ic Company Repo	rt #8-98279-091A			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 0.1 MG (1/2		Attention	Health	Clonidine Tablets	PS		ORAL

TABLET TWIC		Deficit/Hyperactivity	Professional				
		Disorder					P
DAILY) ORA	L	Condition Aggravated		Adderall	SS		ORAL
5 MG TWICE		Hostility					P
DAILY ORAL							ŗ
		Muscle Twitching Speech Disorder		Adderall Dextromphetamine	C		ŗ
				Sulfate	C		ľ
							ļ
	99ISR Number: Gender:Femal	: 3273090-XReport Type:Direct le I/FU:I	Company Repor	t #			I
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Medication Error		Adderall 5 Mg-Mfr-Shire			
15 MG Q DAI	LY			Richwood, Inc.	PS	Shire Richwood, Inc.	ORAL
PO							
		: 3278838-6Report Type:Direct	Company Repor	·t #			
Age:	Gender:	I/FU:I					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Body Temperature Increased Drug Effect Decreased		Adderall (20mg Tablets)	PS	Richwood	

Date:08/23/99ISR Number: 3333252-XReport Type:Direct Company Report # Age: Gender:Male PT Report Source Product Role Manufacture Dose Duration Attention Deficit/Hyperactivity Disorder Condition Aggravated Feeling Jittery Impulsive Behaviour Nervousness PS Richwood Pharmaceuti Date:08/25/99ISR Number: 3333925-9Report Type:Direct Company Report # Age:51 YR Gender:Male I/FU:I Company Report # Outcome PT Report Source Product Role Manufacture Dose Duration Other Abnormal Dreams Consumer Adderall 10mg Defice:Onsumer Adderall 10mg Tablets, Mfd By Shire Richwood PS Mfd By Shire Richwood	
Dose Duration Attention Deficit/Hyperactivity Disorder Condition Aggravated Feeling Jittery Impulsive Behaviour Nervousness Date:08/25/99ISR Number: 3333925-9Report Type:Direct Age:51 YR Gender:Male DT Outcome Dose Duration Other Abnormal Dreams Other Abnormal Dreams Decreased Appetite Depression Drug Ineffective 7.5 MG, 3 OR Restlessness Attention Attention Attention Attention Adderall 10mg Tablets Adderall 10mg Tablets, Mfd By Shire Richwood PS Mfd By Shire Richwood PS Mfd By Shire PS Mfd By Shire Richwood PS Mfd By S	
Attention       Adderall 10mg         Deficit/Hyperactivity       Tablets       PS         Disorder       Condition Aggravated         Feeling Jittery       Impulsive Behaviour         Nervousness       Impulsive Behaviour         Date:08/25/99ISR Number:       3333925-9Report Type:Direct       Company Report #         Age:51 YR       Gender:Male       I/FU:I         Outcome       PT       Report Source       Product         Dose       Duration       Consumer       Adderall 10mg         Other       Abnormal Dreams       Consumer       Adderall 10mg         Decreased Appetite       Tablets, Mfd By       PS         Depression       Shire Richwood       PS         7.5 MG, 3 OR       Restlessness       Restlessness	er Route
Age:51 YR Gender:Male I/FU:I Outcome PT Report Source Product Role Manufacture Dose Duration Other Abnormal Dreams Consumer Adderall 10mg Decreased Appetite Tablets, Mfd By Depression Drug Ineffective Richwood PS Mfd By Shir Restlessness	ical
Dose Duration Other Abnormal Dreams Consumer Adderall 10mg Decreased Appetite Tablets, Mfd By Depression Drug Ineffective Richwood PS Mfd By Shir Restlessness	
Other Abnormal Dreams Consumer Adderall 10mg Decreased Appetite Tablets, Mfd By Depression Drug Ineffective Richwood PS Mfd By Shir Restlessness Restlessness	er Route
7.5 MG, 3 OR Restlessness	re
Date:09/01/99ISR Number: 3338667-1Report Type:Direct Company Report # Age:59 YR Gender:Male I/FU:I	
Outcome PT Report Source Product Role Manufacture	er Route
Dose Duration	
Other Aggression Adderall 10mg Attention Tablets PS Richwood Deficit/Hyperactivity Pharmaceuti Disorder Condition Aggravated Feeling Jittery Irritability	ical

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 1 1/2 PO BID		Dizziness		Adderall 10mg	PS		ORAL
1 1,2 10 515		Orthostatic Hypotension					
Date:10/01/9 Age:43 YR (		: 3361466-1Report Type:Direct le I/FU:I	Company Repor	t #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Extrasystoles	Health	Adderall 10 Mg	PS	Shire Richwood	ORAL
10MG TABLETS		Feeling Abnormal	Professional				
oral 3x day		reeiing Abnormar	PIOLESSIONAL				
		Palpitations					
Date:10/07/9 Age:21 YR (		: 3366392-XReport Type:Direct le I/FU:I	Company Repor	t #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Agitation		Adderall 10 Mg			
		Condition Aggravated		Tablets	PS		
10MG 2X/DAY					~		
		Disturbance In Attention Drug Ineffective		Paxil Ralafen	C C		
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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Msm	С
Vitamin E	С
Multivitamins	С

Date:12/03/99ISR Number: 3413418-OReport Type:Expedited (15-DaCompany Report #US99168 Age:12 YR Gender:Male I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other BID		Testicular Neoplasm	Health	Adderall	PS	
ыл			Professional			

Date:12/08/99ISR Number: 3416579-2Report Type:Expedited (15-DaCompany Report #9949846 Age:13 YR Gender:Female I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - 50.00 MG	Blood Pressure Increased	Literature	Zoloft Tablets	PS	ORAL
Initial or Prolonged TOTAL:DAILY:0	Chest Pain	Health			
	Dyspnoea	Professional			
RAL 30.00 MG	Dyspnoea Exertional		Methylphenidate	SS	ORAL
50.00 Mg	Hyperhidrosis				
TOTAL:BID:ORA	Nodal Arrhythmia				
L 10.00 MG	Palpitations		Adderall	SS	ORAL
10.00 110	Paraesthesia				
TOTAL:DAILY:O	Tachycardia				

RAL

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization	ration - 4 WK	Abnormal Behaviour	Health	Adderall	PS		ORAL
Initial or Prol Other	onged	Aggression Emotional Disorder Hostility Muscle Spasms Muscle Twitching Obsessive-Compulsive Disorder Psychotic Disorder Speech Disorder Tourette'S Disorder	Professional	Claritin (Loratadine)	С		
	R Number: der:	3422794-4Report Type:Direct I/FU:I	Company Report	t #			
Outcome Dose Du	ration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Alopecia Areata		Adderal	PS	Shire Richwood , Inc	
Date:12/17/99IS Age:15 YR Gen		3424916-8Report Type:Expedite I/FU:I	ed (15-DaCompany Report	t #US99202			
Outcome Dose Du	ration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization		Leukopenia	Health	Adderall	PS		ORAL
Initial or Prol AND NOON	onged	Neutropenia	Professional				
				Acetominophen	С		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Route

ORAL

Route

ORAL

ORAL

Route

Date:12/17/99ISR Number Age: Gender:Male	: 3425631-7Report Type:Exped e I/FU:I	lited (15-Da	Company Repor.	t #US99202		
Outcome	PT	Report S	ource	Product	Role	Manufacturer
Dose Duration						
Hospitalization - 10MB PO AM	Attention			Adderall	PS	
Initial or Prolonged AND NOON	Deficit/Hyperactivity					
	Disorder			Acetaminophen	С	
	Condition Aggravated					
	Leukopenia					
Date:12/17/99ISR Number Age:9 YR Gender:Male	: 3440417-5Report Type:Perio e I/FU:I	odic	Company Repor	t #9836702		
Outcome	PT	Report S	ource	Product	Role	Manufacturer
Dose Duration						
Hospitalization -	Stevens-Johnson Syndrome	Consumer		Zithromax Pediatric		
Initial or Prolonged	Vomiting	Health		Oral Suspension	PS	
ORAL			_			
Required		Professi	onal	Adderall	SS	
ORAL					a	
Intervention to				Prednisone Dexedrine	C C	
Prevent Permanent Impairment/Damage				Dexearine	C	
Date:12/27/99ISR Number Age:14 YR Gender:Male	r: 3431464-8Report Type:Exped e I/FU:F	lited (15-Da	Company Repor	t #US99158		
Outcome	PT	Report S	ource	Product	Role	Manufacturer
Dose Duration	Dlagding Wine Duclarged	TToolth		7 4 4 9 9 9 1 7	DC	
Hospitalization - NOT PROVIDED	Bleeding Time Prolonged	Health		Adderall	PS	
Initial or Prolonged NOT PROVIDED	Fibroma	Professi	onal	Ibuprofen	SS	
Other	Haematoma					
Required	Haemorrhage					
Intervention to	Platelet Disorder					
Prevent Permanent Impairment/Damage						

Date:01/31, Age:	1/00ISR Number Gender:	r: 3447841-5Report Type:Direct I/FU:I	Company Repor	:t #			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Hallucination, Auditory Psychotic Disorder		Adderall	PS		
Date:01/31, Age:11 YR		r: 3448660-6Report Type:Expedit e I/FU:I	ed (15-DaCompany Repor	st #US00001			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 45MG	DULALION	Faecal Incontinence	Health	Adderall	PS		
BID/(MANY		Grand Mal Convulsion	Professional				
BID7 (MANY YEAR)		Urinary Incontinence					
I EAR /				Guanfacine Tenex (Guanfacine)	SS C		
Date:02/16, Age:	6/00ISR Number Gender:	r: 3458799-7Report Type:Periodi I/FU:I	ic Company Repor	ct #US00016			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Convulsion	Health Professional	Adderall	PS		

				Event Reporting Syste f Information (FOI) Re		
Date:02/18/0 Age:10 YR		3459227-8Report Type:Direct I/FU:I	Company Repor	t #		
Outcome Dose	Duration	PT Drowning	Report Source	Product Adderall	Role Manufacturer	Route ORAL
Death 10 MG TWICE		Drowning		Adderall	PS	UKAL
DAY (8 AM AN	D					
NOON) ORALLY						
	0ISR Number: Gender:Male	3466363-9Report Type:Periodic I/FU:I	c Company Repor	t #9913973		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 25.00 MG		Apathy	Consumer	Zoloft Tablets	PS	ORAL
TOTAL: DAILY	:	Depression	Health			
ORAL		Drug Ineffective	Professional			
ORAL				Adderall	SS	ORAL
				Claritin Allegra	C C	
Date:03/06/0 Age:20 YR		3471044-1Report Type:Expedite	ed (15-DaCompany Repor	t #US00028		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Required 20 MG PO	Durución	Convulsion	Consumer	Adderall	PS	ORAL
Intervention DAILY	to	Epileptic Aura				
Prevent Perm Impairment/D		Joint Stiffness Loss Of Consciousness				

	0ISR Number Gender:Male	: 3471045-3Report Type:Exped: I/FU:I	ited (15-DaCompany Re	port #US00026			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Death 10 MG PO BID		Abdominal Pain	Health	Adderall	PS		ORAL
		Drowning Drug Level Above Therapeutic Fatigue	Professional				
Date:03/06/00 Age:25 YR (		: 3471046-5Report Type:Exped: I/FU:I	ited (15-DaCompany Re	port #US00025			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Death		Completed Suicide	Consumer	Adderall	PS		
ONCE DAILY	3 WK			Effexor	С		
	0ISR Number Gender:Male	: 3472327-1Report Type:Exped: I/FU:F	ited (15-DaCompany Re	port #US99202			
Outcome Hospitalizat: Initial or P:		PT Aggression Attention Deficit/Hyperactivity Disorder Condition Aggravated Differential White Blood Cell Count Abnormal Drug Ineffective					
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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Dose	Duration	Hostility Leukopenia Lymphadenopathy	Report Source	Product	Role	Manufacturer	Route
DOSE	Duracion	Neutropenia	Health	Adderall	PS		ORAL
10 MG PO AM			Professional				
AND NOON				Acetaminophen	С		
	0ISR Number Gender:Fema	: 3475900-XReport Type:Expedit le I/FU:I	ed (15-DaCompany Repor	t #US00038			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat		Cerebral Artery Occlusion	Consumer	Adderall	PS		
20MG PO Q AM Initial or P		Cerebrovascular Accident Embolism Hemiplegia	Health Professional	Paxil Lactobacillus Echinacea	C C C		
	OISR Number Gender∶Male	: 3479034-XReport Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #00031501			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Required Intervention Prevent Perm Impairment/D	to anent	Convulsion	Health Professional Company Representative	Adderall Shire Richwood	PS		
Date:03/23/0 Age:19 MON		: 3478976-9Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #2000030022			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat Initial or P		Accidental Exposure Insomnia Irritability	Health Professional	Ryna-12 S Suspension (Pyrilamine Tannate, Phehnylephrine			
1/2 TEASPOON	,	Muscle Twitching		Tannate)	PS		ORAL

PO	Mydriasis				
I	Restlessness		Adderall		
DATA NA, PO	Speech Disorder		(Amphetamine)	SS	ORAL
	Toxicologic Test Abnormal				
Date:03/23/00ISR Number: Age:9 YR Gender:Male	3479104-6Report Type:Direct I/FU:I	Company Report	t #		
Outcome I Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
	Hallucination, Auditory		Adderall 5 Mg	PS	ļ
Initial or Prolonged	Psychotic Disorder Thinking Abnormal		Imipramine	С	
Date:04/06/00ISR Number: Age:9 YR Gender:Female	3484735-3Report Type:Direct e I/FU:I	Company Report	t #		
Outcome I Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
	Convulsion	Health	Adderall	PS	
	Eye Rolling	Professional			
7.5; X 2	Tremor				
WEEKS 2 WK					

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:04/19/00ISR Number: 3489571-XReport Type:Direct Company Report # Gender:Female Age:42 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Life-Threatening Medication Error Adderall PS ORAL ORAL ORAL Cylert SS ORAL Date:04/24/00ISR Number: 3491976-8Report Type:Expedited (15-DaCompany Report #US00052 Age: Gender:Male I/FU:I ΡТ Report Source Role Manufacturer Product Outcome Route Dose Duration Dermatitis Bullous Hospitalization -Literature Adderall PS ORAL 5 MG, PO, BID Initial or Prolonged Erythema Multiforme Health Herpes Simplex Professional Mouth Ulceration Pyrexia Rash Erythematous Date:05/15/00ISR Number: 3499982-4Report Type:Direct Company Report # Gender:Female Age:10 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Required Headache Adderall 25mg PS 25MG 7AM + 4P Intervention to Hypertension Prevent Permanent Insomnia Impairment/Damage Sleep Disorder Date:05/17/00ISR Number: 3502765-XReport Type:Expedited (15-DaCompany Report #US0007700 Age:18 YR Gender:Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Convulsion Adderall 10 PS Shire Richwood Inc 330 MG ONCE

Initial	or	Prolonged	Intentional	Misuse
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Date:05/24/00ISR Numbe Age: Gender:Fem	er: 3504544-6Report Type:Dire nale I/FU:I	ect Company Re	eport #			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 1 TABLE 4	Anaphylactic Shock Hypersensitivity		Adderall 10mg Richwood	PS	Richwood	ORAL
TIMES ORAL						
Age:8 YR Gender:Mal Outcome	er: 3506462-6Report Type:Expe .e I/FU:I PT	edited (15-DaCompany Re Report Source	eport #US0007800 Product	Role	Manufacturer	Route
Age:8 YR Gender:Mal Outcome Dose Duration Hospitalization -	.e I/FU:I		-	Role PS	Manufacturer Shire Richwood Inc	Route
Age:8 YR Gender:Mal Outcome Dose Duration	e I/FU:I PT	Report Source	Product			Route

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:06/20/00ISR Number: 3516393-3Report Type:Expedited (15-DaCompany Report #US0009500 Age:10 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Abnormal Behaviour Health Adderall 10 PS Shire Richwood Inc 10 MG BID Initial or Prolonged Aggression Professional Eye Rolling Hostility Trance Date:06/20/00ISR Number: 3516759-1Report Type:Expedited (15-DaCompany Report #US0009700 Aqe:16 YR Gender:Male I/FU:I PTRole Manufacturer Outcome Report Source Product Route Dose Duration Hospitalization -Confusional State Health Adderall PS Professional Initial or Prolonged Hyperventilation С Depakote Irritability Seroquel С С Pyrexia Prozac Tachycardia Synthroid С Tachypnoea Thinking Abnormal Vomiting Date:06/21/00ISR Number: 3517168-1Report Type:Expedited (15-DaCompany Report #US0009600 Age:15 YR Gender:Female I/FU:I Outcome  $\mathbf{PT}$ Product Role Manufacturer Report Source Route Duration Dose Hospitalization -Health Adderall Shire Laboratories Arrhythmia PS Initial or Prolonged Cyanosis Professional Inc Grand Mal Convulsion Hypertension Medication Error Overdose Speech Disorder

Vomiting

01SR Number: Gender:Male	: 3522628-3Report Type:Peri I/FU:I	odic Company Re	port #US9908900			
Dunction	PT	Report Source	Product	Role	Manufacturer	Route
	Drug Ineffective	Consumer	Adderall	PS	Shire Richwood Inc	
	: 3522629-5Report Type:Peri I/FU:I	odic Company Re	port #US9910400			
Duration	PT	Report Source	Product	Role	Manufacturer	Route
Duración	Skin Discolouration	Consumer	Adderall	PS	Shire Richwood Inc	
	: 3522631-3Report Type:Peri I/FU:I	odic Company Re	port #US9910500			
Duration	PT	Report Source	Product	Role	Manufacturer	Route
Duración	Drug Ineffective	Health	Adderall	PS	Shire Richwood Inc	
		Professional				
	Gender:Male Duration CY OOISR Number: Gender:Male Duration	Gender:Male I/FU:I PT Duration Drug Ineffective LY DOISR Number: 3522629-5Report Type:Peri Gender:Male I/FU:I PT Duration PT Skin Discolouration DOISR Number: 3522631-3Report Type:Peri Gender:Male I/FU:I PT Duration	Gender:MaleI/FU:IPTReport SourceDurationDrug IneffectiveConsumerDUS522629-5Report Type:PeriodicCompany Regord SourceOOISR Number:3522629-5Report Type:PeriodicCompany Regord SourceDurationPTReport SourceDurationSkin DiscolourationConsumerOOISR Number:3522631-3Report Type:PeriodicCompany Regord SourceOOISR Number:3522631-3Report Type:PeriodicCompany Regord SourceDurationPTReport SourceDurationPTReport SourceDurationDrug IneffectiveHealth	Gender:MaleI/FU:IDurationPTReport SourceProductDrug IneffectiveConsumerAdderallOUISR Number:3522629-5Report Type:PeriodicCompany Report #US9910400DurationPTReport SourceProductDurationSkin DiscolourationConsumerAdderallOUISR Number:3522631-3Report Type:PeriodicCompany Report #US9910500OUISR Number:3522631-3Report Type:PeriodicCompany Report #US9910500OUISR Number:3522631-3Report Type:PeriodicCompany Report #US9910500OUISR Number:3522631-3Report Type:PeriodicCompany Report #US9910500OUISR Number:3522631-3Report Type:PeriodicCompany Report #US9910500OurationPTReport SourceProductDurationPTReport SourceProductDurationMagineffectiveHealthAdderall	Gender:MaleI/FU:IDurationPTReport SourceProductRoleDurg IneffectiveConsumerAdderallPSOUISR Number:3522629-5Report Type:Period:Company Report #US9910400RoleDurationPTReport SourceProductRoleDurationSin DiscolourationConsumerAdderallPSOUISR Number:3522631-3Report Type:Period:Company Report #US9910500RoleOUISR Number:3522631-3Report Type:Period:Company Report #US9910500RoleOUISR Number:3522631-3Report Type:Period:Company Report #US9910500RoleOurationPTReport SourceProductRoleDurationPTReport SourceProductRoleDurationI/FU:IKeport SourceProductRoleDurationPTReport SourceProductRoleDurationJug IneffectiveHealthAdderallPS	Gender:Male       I/FU:I         Duration       FT       Report Source       Product       Role       Manufacturer         Duration       Drug Ineffective       Consumer       Adderall       PS       Shire Richwood Inc         OUISR Number:       3522629-5Report Type:Period:       Company Report #US9910400       FT       Report Source       Product       Role       Manufacturer         Duration       PT       Report Source       Product       Role       Manufacturer         Duration       Stizz631-3Report Type:Period:       Company Report #US9910500       FT       Shire Richwood Inc         OUISR Number:       3522631-3Report Type:Period:       Company Report #US9910500       FT       Shire Richwood Inc         OUISR Number:       11/FU:I       Company Report #US9910500       FT       Shire Richwood Inc         Duration       PT       Report Source       Product       Role       Manufacturer         Duration       FT       Report Source       Product       Role       Shire Richwood Inc         Duration       Ing Ineffective       Health       Adderall       PS       Shire Richwood Inc

			FDA - Adverse	e Event Reporting Syste	em (AEF	S)	
			Freedom C	)f Information (FOI) Re	port		
	0ISR Number: Gender:Male	: 3522633-7Report Type:Periodi I/FU:I	c Company Repor	rt #US9910600			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10 MG Q AM	3 mon	Dysarthria Dysphemia Speech Disorder	Consumer	Adderall 10	PS	Shire Richwood Inc	
	0ISR Number: Gender:Male	: 3522634-9Report Type:Periodi I/FU:I	c Company Repor	rt #US-99-107-00			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10MGQD	Duración	Antinuclear Antibody	Health	Adderall 10	PS	Shire Richwood Inc	
TOMGQD		Positive	Professional	Acetaminophen Prn (Headaches)- Dose Not Provided	С		
Date:06/29/0 Age:37 YR		: 3522636-2Report Type:Periodi le I/FU:I	c Company Repor	rt #US9910800			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 20 MG DAILY	Duración	Agitation	Consumer	Adderall 10	PS	Shire Richwood Inc	
20 NG DATET				Gabapertin Clonaxepam Neurontin Klonopin 	C C C C C		
	0ISR Number: Gender:Male	: 3522639-8Report Type:Periodi I/FU:I	c Company Repor	rt #US9910900			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10 MG PO		Emotional Disorder	Consumer	Adderall 10	PS	Shire Richwood Inc	ORAL

Personality 1	Disorder
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	01SR Number: Gender:Male	3522641-6Report Type:Per I/FU:I	riodic	Company Report	#US9911000			
Outcome		PT	Report S	ource	Product	Role	Manufacturer	Route
Dose Other 20 MG	cher	Liver Function Test			Adderall 10	PS	Shire Richwood Inc	
20 MG		Abnormal						
Dacc. 00, 22, 3	NUTSR Number:	3500640-8Report Type:Per	rindia	Company Report	#TTS9911100			
Outcome	Gender:Femal	3522642-8Report Type:Per e I/FU:I PT	riodic Report S	Company Report ource	#US9911100 Product	Role	Manufacturer	Route
Outcome Dose Other	Gender:Femal	e I/FU:I		ource		Role PS	Manufacturer Shire Richwood Inc	Route ORAL
Outcome Dose	Gender:Femal	.e I/FU:I PT	Report S	ource	Product			

			FDA -	Adverse Event Reporting Syste	em (AER	रS )	
			Fr	reedom Of Information (FOI) Re	eport		
Date:06/29/ Age:	00ISR Number Gender:	: 3522643-XReport Type:Period I/FU:I	dic Compan	ny Report #US0001500			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Durución	Hypercholesterolaemia	Health Professional	Adderall 10	PS	Shire Richwood Inc	
Date:06/29/ Age:	00ISR Number Gender:	: 3522644-1Report Type:Period I/FU:I	dic Compan	ny Report #US0001600			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Convulsion	Health Professional	Adderall 10	PS	Shire Richwood Inc	
Date:06/29/ Age:56 YR Outcome Dose	00ISR Number Gender:Fema Duration	: 3522645-3Report Type:Period le I/FU:I PT	dic Compan Report Source	ny Report #US9909200 Product	Role	Manufacturer	Route
Other		Diarrhoea Dyspepsia	Consumer	Adderall 10 Effexor Xr	PS SS	Shire Richwood Inc	ORAL
75 MG PO TI	D	Nausea		Effexor Xr Capsules Seroquel (Quetiapine) Xanax (Alprazolam)	с с с		
Date:06/29/ Age:9 YR	00ISR Number Gender:Male	: 3522646-5Report Type:Period I/FU:I	dic Compan	ny Report #US9913300			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 5 MG PO QD	2 DAY	Dermatitis	Health	Adderall 10	PS	Shire Richwood Inc	ORAL
J MG FO QD			Professional	Clonidine Valproic Acid 	C C C		

Date:06/29/0 Age:9 YR	00ISR Number Gender:Fema	: 3522647-7Report Type:Period le I/FU:I	ic Company Repo	rt #US9913400			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10 MG PO TII		Clonic Convulsion	Health	Adderall 10	PS	Shire Richwood In	nc ORAL
10 10			Professional				
		: 3522648-9Report Type:Period	ic Company Repo	rt #US9913600			
Date:06/29/0 Age:34 YR	00ISR Number Gender:Fema		ic Company Repo	rt #US9913600			
Age:34 YR Outcome Dose		le I/FU:I PT	Report Source	Product	Role	Manufacturer	Route
Age:34 YR Outcome	Gender:Fema	le I/FU:I			Role PS	Manufacturer Shire Richwood In	

				FDA - Adverse	e Event Reporting System	m (AER	s)	
				Freedom O	Of Information (FOI) Rep	port		
Date:06/29/( Age:36 YR	00ISR Number Gender:Fema	: 3522649-0Report Type:Periodia le I/FU:I	С	Company Report	t #US9913700			
Outcome Dose	Duration	PT	Report S	Source	Product	Role	Manufacturer	Route
Dose Other 10 MG Q AM	Duración	Headache	Consumer	r	Adderall 10	PS	Shire Richwood Inc	I
					Ritalin Claritin Nasonex	C C C		
	00ISR Number Gender:Femal	: 3522650-7Report Type:Periodia le I/FU:I	.C	Company Report	t #US9913900			
Outcome	Duration	PT	Report S	Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Psychotic Disorder	Health		Adderall 10	PS	Shire Richwood Inc	I
20 MG QD	4 MON		Professi Company Represer	<del>,</del>				
	00ISR Number Gender:Fema	: 3522651-9Report Type:Periodio le I/FU:I	.C	Company Report	t #US9914000			
Outcome		PT	Report S	Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Myalgia	Health		Adderall	PS	Shire Richwood Inc	ORAL
10MG POQAM			Professi	ional				
Date:06/29/( Age:35 YR	00ISR Number Gender:Male	: 3522652-0Report Type:Periodio I/FU:I	С	Company Report	t #US9914100			
Outcome		PT	Report S	Source	Product	Role	Manufacturer	Route
Dose Other TID	Duration	Hepatic Function Abnormal	Health		Adderall 10	PS	Shire Richwood Inc	
			Professi	ional				

	01SR Nu Gender:		: 3522654-4Report Type:Periodi le I/FU:I	c Company Report	t #US9914200			
Outcome Dose	Durati	on	PT	Report Source	Product	Role	Manufacturer	Route
Other			Supraventricular	Health	Adderall 10	PS	Shire Richwood Inc	
10 MG QD	18	DAY	Tachycardia	Professional	Sertraline	SS		
50 MG QD	6	MON			Zoloft (Sertraline)	С		
Age:44 YR	01SR Nu Gender:					- 1		
Outcome Dose	Durati	on	РТ	Report Source	Product	Role	Manufacturer	Route
Other 20 MG TID PC	) 5	MON	Drug Dependence	Consumer	Adderall 20	PS		ORAL
	01SR Nu Gender:		: 3522694-5Report Type:Periodi I/FU:I	c Company Report	t #US9919800			
Outcome Dose	Durati	<u>en</u>	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 10MG QD PO	Durati	.011	Angiopathy	Consumer	Adderall	PS	Shire Richwood Inc	ORAL

			FDA – Ac	FDA - Adverse Event Reporting System (AERS)							
			Freedom Of Information (FOI) Report								
Date:06/29, Age:33 YR	ate:06/29/00ISR Number: 3522695-7Report Type:Periodi ge:33 YR Gender:Female I/FU:I			c Company Report #US9919900							
Outcome		PT	Report Source	Product	Role	Manufacturer	Route				
Dose Other 80MG-100MG	Duration QD	Psychotic Disorder	Consumer	Adderall	PS	Shire Richwood Inc					
Date:06/29, Age:6 YR	/00ISR Number Gender:Male	r: 3522696-9Report Type:Pe e I/FU:I	riodic Company	Report #US9919200							
Outcome		PT	Report Source	Product	Role	Manufacturer	Route				
Dose Hospitaliza 20MG(AM)+20 Initial or (PM)	OMG	Psychotic Disorder	Consumer	Adderall	PS	Shire Richwood Inc					
( 211 )				Risperdal Cogentin Albuteral Depakote	C C C						
Date:06/29, Age:	/00ISR Number Gender:Fema	r: 3522697-0Report Type:Pe ale I/FU:I	riodic Company	Report #US9919300							
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route				
Dose Other	Duration	Drug Ineffective	Consumer	Adderall	PS	Shire Richwood Inc					
Date:06/29, Age:	/00ISR Number Gender:	r: 3522698-2Report Type:Pe I/FU:I	riodic Company	Report #US9919400							
Outcome		PT	Report Source	Product	Role	Manufacturer	Route				
Dose Other 2 WK	Duration	Pruritus	Health	Adderall	PS	Shire Richwood Inc					
			Professional								

Date:06/29/ Age:5 YR	00ISR Number: Gender:Male	3522699-4Report Type:Periodi I/FU:I	c Company Repor	t #US9919600			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10MG(AM)+10		Emotional Disorder	Health	Adderall	PS	Shire Richwood Inc	
(PM)			Professional				
Date:06/29/ Age:7 YR	00ISR Number: Gender:Male	3522700-8Report Type:Periodi I/FU:I	c Company Repor	t #US9918900			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 7.5MG(AM)+5		Vomiting	Health	Adderall	PS	Shire Richwood Inc	
(PM)			Professional				
Date:06/29/ Age:39 YR	00ISR Number: Gender:Femal	3522701-XReport Type:Periodi .e I/FU:I	c Company Repor	t #US9918700			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 5MG-10MG		Emotional Disorder	Consumer	Adderall	PS	Shire Richwood Inc	
DAILY		Headache					

				FDA - Adve	rse Event Reporting S	System (AER	S)	
				Freedo	m Of Information (FO	I) Report		
Date:06/29/0 Age:10 YR	00ISR Number Gender:Male	: 3522702-1Report Type:E I/FU:I	Periodic	Company Re	port #US9920000			
Outcome		PT	Report S	Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Alopecia	Consumer	2	Adderall	PS	Shire Richwood Inc	ORAL
20 MG QD PO					Genotropin	С		
Date:06/29/0 Age:8 YR	00ISR Number Gender:Male	: 3522703-3Report Type:E I/FU:I	Periodic	Company Re	port #US9920100			
Outcome		PT	Report S	Source	Product	Role	Manufacturer	Route
Dose Other 10MG QD	Duration	Drug Ineffective	Consumer		Adderall	PS	Shire Richwood Inc	
Date:06/29/( Age:	00ISR Number Gender:	: 3522704-5Report Type:E I/FU:I	Periodic	Company Re	port #US9920300			
Outcome	Duration	PT	Report S	Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Mania	Health Professi Company Represen		Adderall Singulair	PS SS	Shire Richwood Inc	
Date:06/29/0 Age:13 YR	00ISR Number Gender:Fema	: 3522705-7Report Type:F le I/FU:I	veriodic	Company Re	port #US9920400			
Outcome	Duration	PT	Report S	Source	Product	Role	Manufacturer	Route
Dose Other 20MC ODM	DULACION	Rash Maculo-Papular	Health		Adderall	PS	Shire Richwood Inc	
20MG QAM		Urticaria	Professi	onal	Zoloft	С		
4								

Date:06/29/00ISR Number: 3522706-9Report Type:Periodic Age:9 YR Gender:Male I/FU:I

Company Report #US9918400

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 30 MG DAILY	Duration 1 YR	Glaucoma	Consumer	Adderall	PS	Shire Richwood Inc	
	0ISR Number Gender:Male	: 3522707-0Report Type:Periodic I/FU:I	c Company Repor	t #US9918500			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10MG PO QAM	Duración	Dry Mouth	Health	Adderall	PS	Shire Richwood Inc	ORAL
		Hyperventilation Tachycardia Tremor	Professional				
	0ISR Number Gender:Fema	: 3522709-4Report Type:Periodio le I/FU:I	c Company Repor	t #US9916000			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10MG BID	Duración	Drug Ineffective	Consumer	Adderall 10	PS	Shire Richwood Inc	
			Health Professional				

			FDA - Adver:	se Event Reporting Syste	em (AEF	RS)	
			Freedom	Of Information (FOI) Re	eport		
	0ISR Number Gender:Fema	: 3522711-2Report Type:Periodi le I/FU:I	c Company Repo	ort #US9916100			
Outcome	Dunch	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 20MG PO DAIL	Duration	Drug Ineffective	Consumer	Adderall 10	PS	Shire Richwood Inc	ORAL
ZUMG PU DAIL	1 I			Melatonin	С		
	0ISR Number Gender:Fema	: 3522712-4Report Type:Periodi le I/FU:I	c Company Repo	ort #US9916200			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 20MG BID	Duration	Drug Ineffective	Consumer	Adderall 10	PS	Shire Richwood Inc	
	3 YR			Melatonin	SS		
Q HS				Melatonin	С		
	0ISR Number Gender:Fema	: 3522713-6Report Type:Periodi le I/FU:I	c Company Repo	ort #US9916300			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 20MG PO BID	11 MON	Drug Ineffective	Consumer	Adderall 10	PS	Shire Richwood Inc	ORAL
3MG HS	II MON			Melatonin	SS		
	0ISR Number Gender:Male	: 3522714-8Report Type:Periodi I/FU:I	c Company Repo	ort #US9916400			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 7.5 MG (FREQ		Drug Ineffective	Consumer	Adderall 10	PS	Shire Richwood Inc	

UNK.)

Date:06/29/0 Age:	00ISR Number Gender:Fema	r: 3522715-XReport Type:Periodicale I/FU:I	С	Company Report	t #US9916500			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other 5MG PO QD	1 WK	Emotional Disorder	Health		Adderall 10	PS	Shire Richwood Inc	
	1		Profess	sional				
Date:06/29/0 Age:40 YR	00ISR Number Gender:Fema	r: 3522716-1Report Type:Periodic ale I/FU:I	.C	Company Report	t #US9911500			
Outcome	Devetion	PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other 20MG PO	Duration	Stupor	Health		Adderall 10	PS	Shire Richwood Inc	ORAL
BID-TID			Profess	sional				
Date:06/29/0 Age:9 YR	001SR Number Gender:Male	r: 3522717-3Report Type:Periodia e I/FU:I	.C	Company Report	t #US9911800			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Hospitalizat 20MG PO DAII	ation -	Psychotic Disorder	Health		Adderall 10	PS	Shire Richwood Inc	ORAL
Initial or D			Profess	sional				l

				Erront Donowting Creat	om (AET		
				e Event Reporting Syste		S)	
			Freedom O	Of Information (FOI) Re	port		
Date:06/29/( Age:	00ISR Number: Gender:Male	: 3522718-5Report Type:Periodic	c Company Repor	't #US9911900			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Vasospasm	Health	Adderall 10	PS	Shire Richwood Inc	ORAL
20MG PO BID			Professional				
	00ISR Number: Gender:Femal	: 3522719-7Report Type:Periodic le I/FU:I	c Company Repor	t #US9912000			
Outcome			Report Source	Product	Role	Manufacturer	Route
Dose Other 30MG DAILY	Duration	Peripheral Coldness	Consumer	Adderall 10	PS	Shire Richwood Inc	
30MG DAILI		Ulcer		Naprosyn Levathyroid	C C		
	00ISR Number: Gender:Male	: 3522720-3Report Type:Periodic	c Company Repor	:t #US9912100			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 7.5 MG AM +	Duration	Pruritus	Consumer	Adderall 10	PS	Shire Richwood Inc	
5MG PM							
Date:06/29/( Age:12 YR	00ISR Number: Gender:Male	: 3522721-5Report Type:Periodic I/FU:I	c Company Repor	:t #US9916700			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 15 MG PO Q <i>B</i>		Liver Function Test	Health	Adderall 10	PS	Shire Richwood Inc	ORAL
15 MG PU Q F		Abnormal	Professional				

Date:06/29/ Age:51 YR	00ISR Number: Gender:Male	3522722-7Report Type:Perio I/FU:I	dic Company	Report #US9916900			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10MG BID		Feeling Jittery	Consumer	Adderall 10	PS	Shire Richwood Inc	
		Headache					
(30MG TAB)	1 WK						
		Nausea Tinnitus					
Date:06/29/ Age:7 YR Outcome	Gender:	3522723-9Report Type:Perio	dic Company Report Source	Report #US9917000 Product	Role	Manufacturer	Route
Dose	Duration				-		
Other		Constipation	Health Professional	Adderall 10	PS	Shire Richwood Inc	
Date:06/29/ Age:16 YR	00ISR Number: Gender:Male	3522724-0Report Type:Perio	dic Company	Report #US9917100			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Nephrolithiasis	Health Professional	Adderall 10	PS	Shire Richwood Inc	

			FDA – Adve	erse Event Reporting S	System (AEF	RS)	
			Freedo	om Of Information (FO	[) Report		
Date:06/29/0 Age:7 YR	00ISR Number Gender:Male	: 3522725-2Report Type:Peric I/FU:I	odic Company Re	eport #US9917200			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10MG PO QD	Duración	Emotional Disorder	Health	Adderall 10	PS	Shire Richwood Inc	ORAL
			Professional	Vitamin A	C		
Date:06/29/0 Age:8 YR	00ISR Number Gender:Fema	: 3522726-4Report Type:Peric le I/FU:I	odic Company Re	eport #US9917300			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 5MG PO BID	Duración	Hallucination, Auditory	Other	Adderall 10	PS	Shire Richwood Inc	ORAL
	00ISR Number Gender:	: 3522727-6Report Type:Peric I/FU:I	odic Company Re	eport #US9917400			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 20 MG PO Q I	AM 2 YR	Blood Cholesterol	Consumer	Adderall 10	PS	Shire Richwood Inc	
10 110 10 <u>v</u>		Increased		Lecithiin Vitamins Pepcid	C C C		
	00ISR Number Gender:Male	: 3522728-8Report Type:Peric I/FU:I	odic Company Re	eport #US9917500			
Outcome	Dunnation	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 15MG QAM +	Duration	Gynaecomastia	Consumer	Adderall 10	PS	Shire Richwood Inc	
10MG QPM	5 YR			Claritin Albuteral	C C		

	00ISR Number Gender:Male	r: 3522729-XReport Type:Period e I/FU:I	dic Company Rep	port #US9917600			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 5MG QD	Duration 5 DAY	Dermatitis	Consumer	Adderall 10	PS	Shire Richwood Inc	
	J DAI			Claritin	С		
	00ISR Number Gender:Male	r: 3524944-8Report Type:Period e I/FU:I	lic Company Rej	port #US9911200			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 20 MG DAILY		Hepatic Function Abnormal	Consumer	Adderall 10	PS	Shire Richwood Inc	
20 110 211-1		Liver Function Test Abnormal					
	00ISR Number Gender:Fema	r: 3525833-5Report Type:Period ale I/FU:I	lic Company Rej	port #US9911400			
Outcome	Derection	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 20 MG. QAM B	Duration	Hallucination	Consumer	Adderall 10	PS	Shire Richwood Inc	ORAL
20 MG. QAM F	<i>j</i> U			Depakote And Tenex For Sleep	С		

				FDA - Adverse	Event Reporting System	m (AER	٤S )	
					f Information (FOI) Rep			
Date:06/29/( Age:8 YR	00ISR Number: Gender:Male	: 3525837-2Report Type:Periodio I/FU:I	.C	Company Report	t #US0001200			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other 12.5 M QD	6 MON	Psychotic Disorder I	Consume: Health Profess		Adderall 30	PS	Shire Richwood Inc	
	00ISR Number: Gender:Male	: 3525840-2Report Type:Periodic I/FU:I	.C	Company Report	t #US0001100			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other 20 MG QAM		Vasodilatation	Consume:	r	Adderall 10	PS	Shire Richwood Inc	
	00ISR Number: Gender:Femal	: 3525842-6Report Type:Periodi le I/FU:I	.C	Company Report	t #US9910200			
Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other 40 MG DAILY		Dysphagia	Consume:	r	Adderall 10	PS	Shire Richwood Inc	
		: 3525845-1Report Type:Periodi I/FU:I	.C	Company Report	t #US9910100			
Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Convulsion	Health		Adderall 10	PS	Shire Richwood Inc	
20 MG Q AM			Profess	ional	Mellaril	С		
1								

Date:06/29/00ISR Number: 3525847-5Report Type:Periodic Age:36 YR Gender:Female I/FU:I Company Report #US9910000

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 30MG PO BID		Myalgia	Consumer	Adderall 10	PS	Shire Richwood Inc	ORAL
	0ISR Number Gender:Fema	: 3525849-9Report Type:Periodi le I/FU:I	c Company Repor	t #US9909900			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 5MG PO AM AN		Muscle Twitching	Health	Adderall 10	PS	Shire Richwood Inc	ORAL
	D	Tic	Professional				
NOON				Claritin	С		
Date:06/29/0 Age:12 YR Outcome		: 3525855-4Report Type:Periodi I/FU:I PT	c Company Repor Report Source	rt #US9909400 Product	Role	Manufacturer	Route
Dose Other 10MG PO DAIL	Duration Y	Urinary Retention	Consumer	Adderall 10	PS	Shire Richwood Inc	ORAL
Date:06/29/0 Age:15 YR		: 3525858-XReport Type:Periodi I/FU:I	c Company Repor	t #US0002100			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 10MG A.M. 5M		Dizziness	Consumer	Adderall 10	PS	Shire Richwood Inc	
MIDDAY	1 WK			Minocycline	С		
22 7	10.24 334						

			FDA - Advers	e Event Reporting Syste	em (AEF	2S)	
			Freedom	Of Information (FOI) Re	eport		
Date:06/29/ Age:15 YR	00ISR Number Gender:Male	: 3525860-8Report Type:Period I/FU:I	ic Company Repo	rt #US0002100			
Outcome	D	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Other 10MG A.M. 5	Duration 5MG	Dizziness	Consumer	Adderall 10	PS	Shire Richwood Inc	
MIDDAY	1 WK			Minocycline	С		
Date:06/29/ Age:18 YR	00ISR Number Gender:Male	: 3525861-XReport Type:Period I/FU:I	ic Company Repo	rt #US0002000			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other UNK	Duración	Drug Dependence	Consumer	Adderall 10	PS	Shire Richwood Inc	
Date:06/29/ Age:8 YR	/00ISR Number Gender:Male	Rhinitis : 3525863-3Report Type:Period I/FU:I	ic Company Repo	rt #US0001900			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 15 MG BID	Duration 2 MON	Petechiae	Consumer	Adderall 10	PS	Shire Richwood Inc	
Date:06/29/ Age:10 YR	/00ISR Number Gender:Male	: 3525866-9Report Type:Period I/FU:I	ic Company Repo	rt #US0001700			
Outcome	Duran I. I	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 40 MG PO	Duration	Affect Lability	Consumer	Adderall 10	PS	Shire Richwood Inc	ORAL
DIVIDED DOS	SE 1 YR	Hostility					
				Zoloft (Sertraline)	С		

Date:07/03/00ISR Number: 3524675-4Report Type:Expedited (15-DaCompany Report #US0010000 Age:36 YR Gender:Female I/FU:I

Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat 20 MG BID	Duration tion -	Abnormal Behaviour	Consumer	Adderall	PS	Shire Richwood Inc	ļ
Initial or P 20 MG TID	rolonged	Anger		Adderall	SS		ļ
		Barrett'S Oesophagus Decreased Appetite Drug Dependence Feeling Abnormal Gastrointestinal Disorder Insomnia Loss Of Consciousness Paranoia Restlessness Weight Decreased		Alprzolam	С		
	00ISR Number Gender:Male	r: 3526409-6Report Type:Expedito e I/FU:I	.ed (15-DaCompany Repor	t #US0011000			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate	ening	Atrial Fibrillation Cardiac Arrest	Health Professional	Adderall 10	PS	Shire Richwood Inc	

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:07/10/00ISR Number: 3579053-9Report Type:Periodic Company Report #USA013449 Age:46 YR Gender:Female I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Headache Consumer Meridia PS Knoll Pharmaceutical Other Co Sub Basf Corp ORAL 10 MG OD PO Adderall ORAL SS 5 MG BID PO Multivitamins С Antifungal Medication С Date:07/20/00ISR Number: 3532719-9Report Type:Expedited (15-DaCompany Report #US-00-110-01 Age:40 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Atrial Fibrillation Shire Richwood Inc Life-Threatening Health Adderall 10 PS MAXIMUM 20 MG Professional Cardiac Arrest 2 YR DAILY Circulatory Collapse Feeling Abnormal Malaise Nervous System Disorder Ventricular Fibrillation Date:07/24/00ISR Number: 3534227-8Report Type:Expedited (15-DaCompany Report #A0123746A Age:22 YR Gender:Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Duration Dose Death Death Health Wellbutrin PS Glaxo Wellcome Inc ORAL 225 MG PER Professional DAY ORAL 1 YR Company Adderall Representative (Formulation Unknown) (Adderall) SS 20 MG IN THE

Age:17 YR Gender:Ma	le I/FU:I					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration	L					
Hospitalization - 10-30 MG	Aggression		Adderall 10	PS	Shire Richwood Inc	
Initial or Prolonged	Confusional State					
DAILY 7 M	ION					
	Delusion					
	Hallucination, Auditory					
	Medication Error					
	Nystagmus					
	Psychotic Disorder					
Date:08/15/00ISR Numb Age:13 YR Gender:Fe	per: 3551000-5Report Type:Exp male I/FU:I	edited (15-DaCompany Re	eport #US0009900			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration	L					
Other	Grand Mal Convulsion	Health	Adderall 10	PS	Shire Richwood Inc	
15-20 MG						
	Insomnia	Professional				
DAILY 1 M	ION					

Loss Of Consciousness

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:08/18/00ISR Number: 3553877-6Report Type:Expedited (15-DaCompany Report #US0009601 Gender:Female Age:15 YR I/FU:F Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Alcoholism Health Adderall PS Shire Richwood Inc Initial or Prolonged Arrhythmia Professional Cyanosis Grand Mal Convulsion Hypertension Medication Error Overdose Speech Disorder Vomiting Date:08/18/00ISR Number: 3589608-3Report Type:Periodic Company Report #S00-USA-00683-01 Age:22 YR Gender:Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Syncope Health Celexa PS Forest Laboratories Professional Tachycardia Inc ORAL 20 MG QD PO Adderall SS ORAL Company 20 MG BID PO Representative Date:08/22/00ISR Number: 3555682-3Report Type:Expedited (15-DaCompany Report #US0013000 Age:15 YR Gender:Male I/FU:I PTReport Source Role Manufacturer Outcome Product Route Dose Duration Adderall 10 Shire Richwood Inc Death Arrhythmia Literature PS 20 MG DAILY 3 YR Cardiac Arrest Circulatory Collapse Muscle Hypertrophy

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
	Duration				DC		
Death 225 MG DAILY	1	Death YR	Health	Wellbutrin	PS	Shire Richwood Inc	
ZZJ MG DAIDI	± .		Professional	Adderall	SS		
20 MG IN THE							
MORNING	4 1	MON					
			e:Expedited (15-DaCompany Re	eport #US0013400			
Age:9 YR Ge	ender:Ma	ale I/FU:I					
Outcome Dose I	Duratio	PT n	Report Source	Product	Role	Manufacturer	Route
Hospitalizatio 20 MG BID		Amnesia YR	Health	Adderall 10	PS	Shire Richwood Inc	
Initial or Pro	olonged	Confusional State Dehydration Vomiting	Professional				
	ISR Numl ender:Fo		e:Expedited (15-DaCompany Re	eport #US0013600			
Outcome		PT					
Hospitalizatio	on –	Abdominal Pain Upper					
Initial or Pro	olonged	Cardiac Murmur Cardiovascular Disor Crying	der				
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Freedom Of Information (FOI) Report

		Dehydration Fear			_ ]		
Dose	Duration	Heart Rate Decreased	Report Source	Product	Role	Manufacturer	Route
5 MG TWICE	Durución	Medication Error	Consumer	Adderall 10	PS	Shire Richwood Inc	
DAILY	2 MON	Psychomotor Hyperactivity					
20 MG TWICE		Vomiting		Adderall	SS		
	ISR Number ender:Male	: 3584640-8Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	ort #US0015100			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizati Initial or Pr 30 MG BID		Cardiac Enzymes Increased Chest Pain	Health Professional	Adderall	PS	Shire Laboratories Inc	
		Myocardial Infarction Retroperitoneal Haemorrhage		Bupropion Nefazodone Divalproex	C C C		
				Metoprolol	C		
	ISR Number ender:Male	: 3599213-OReport Type:Expedi I/FU:I	ted (15-DaCompany Repo	ort #US-00-172-00			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalizati Initial or Pr UNKNOWN		Aplastic Anaemia Bone Marrow Transplant ID White Blood Cell Count	Health Professional	Adderall	PS	Shire Laboratories Inc	
UNKNOWN	3 DAY						
	ISR Number ender:Fema	: 3600267-3Report Type:Expedi le I/FU:I	ted (15-DaCompany Repo	ort #US0017500			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route

Hospitalization Initial or Prol 5 MG AM	longed I 1 YR	Micturition Disorder Mycoplasma Infection Paraesthesia	Health Professional	Adderall 10	PS	Shire Laboratories Inc	
	SR Number: nder:Male	: 3602957-5Report Type:Expedite I/FU:I	ed (15-DaCompany Report	t #US0017900			
Outcome Dose Du	uration	PT	Report Source	Product	Role	Manufacturer	Route
		Petit Mal Epilepsy	Health Professional	Adderall 10		Shire Laboratories Inc	
5 MG BID							
Date:10/27/00IS Age:34 YR Gen		: 3602958-7Report Type:Expedite le I/FU:I	ed (15-DaCompany Report	t #US0017800			
Outcome Dose Du:	uration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization Initial or Prol	longed	Anxiety Facial Bones Fracture Laceration Psychotic Disorder Road Traffic Accident Thinking Abnormal	Other	Adderall 10		Shire Laboratories Inc	

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:11/01/00ISR Number: 3605436-4Report Type:Expedited (15-DaCompany Report #US0018400 Gender:Female Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Other Dysphemia Health Adderall 10 PS Shire Laboratories Malaise Professional Inc 15 MG QAM; 5 Movement Disorder MG QPM Nightmare С Paxil С Syncope Singular Albuterol С С Pulmicort Zyrtec С Date:11/03/00ISR Number: 3606660-7Report Type:Direct Company Report # Age:15 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Aleve Cold & Sinus Required Chest Pain Intervention to Hypertension 220mg/120mg Bayer PSBayer 1 DAY Prevent Permanent Syncope Adderall 10mg SS 1.5 2 TIMES Impairment/Damage Date:11/03/00ISR Number: 3606685-1Report Type:Direct Company Report # Age:19 YR Gender:Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Abnormal Behaviour Adderall 7.5mg Other PS5 MG MORNI Bipolar Disorder 2.5 EVENIN Ecchymosis Mania Psychomotor Hyperactivity

	00ISR Number: Gender:Male	: 3614160-3Report Type:Periodi I/FU:I	ic Company Repo	ort #FLUV002990039			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Insomnia	Health Professional	Luvox	PS	Solvay Pharmaceuticals	ORAL
DAILY PO							· · · · ·
				Adderall (Combination Of Amphetamines) (Sympathomimetics)	SS		ORAL
DAILY PO							OIGH
	00ISR Number: Gender:Male	: 3614454-1Report Type:Periodi I/FU:I	.ic Company Repo	ort #FLUV002980308			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration		_				
Other		Dizziness Hypertension	Health Professional	Luvox	PS	Solvay Pharmaceuticals	ORAL
SEE IMAGE		21					
4		Migraine		Adderall	SS		ORAL
20 MG DAILY							
PO							

			FDA - Adverse	Event Reporting Syste	em (AER	2S)	
			Freedom O	f Information (FOI) Re	port		
	)0ISR Number Gender:Male	r: 3613516-2Report Type:Expedit e I/FU:I	ed (15-DaCompany Repor	t #US0019800			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death		Leukopenia Neutropenia	Health Professional	Adderall	PS	Shire Laboratories Inc	
20 MG QD	18 MON	Sudden Death					
	)1ISR Number Gender:Fema	r: 3642748-2Report Type:Expedit ale I/FU:I	ed (15-DaCompany Repor	t #US0022900			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or F 15 MG BID PC	cion - Prolonged	Colitis Ischaemic	Health Professional	Adderall 10	PS	Shire Laboratories Inc	ORAL
				Insulin "Blood Thinner" Clopidogrel Acetylsalicylic Acid	С С С С		
	)1ISR Number Gender:Male	r: 3645449-XReport Type:Direct	Company Repor	t #			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Pollakiuria		Adderall (10mg Qd)	PS		
	)1ISR Number Gender:Male	r: 3645452-XReport Type:Direct	Company Repor	t #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Abdominal Pain Upper Decreased Appetite		Adderall (5mg lt Bid)	PS		
5MG BID	3 WK	Insomnia Irritability					

Date:01/11/01ISR Number: 3646707-5Report Type:Expedited (15-DaCompany Report #US0100400 Age:39 YR Gender:Female I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizati Initial or Pr START AT 10	lon -	Anxiety Cerebrovascular Accident	Health Professional	Adderall 10	PS	Shire Laboratories Inc	
MG BID		Decreased Appetite	Company				
MG DID		Irritability Memory Impairment	Representative				
	lISR Number Gender:Femal	: 3655741-0Report Type:Expedite le I/FU:I	ed (15-DaCompany Report	#US0101600			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route

			±			
Dose	Durati	on				
Required		Dysphagia	Health	Adderall 10	PS	Shire Laboratories
Interventior 10MG AM & 5M		Hypertonia	Professional			Inc
Prevent Perm			Company			
PM	3	DAY				
Impairment/I	Damage		Representative	Adderall 5	SS	
				Albuterol	С	

Freedom Of Information (FOI) Report

Date:01/29/01ISR Number: 3656614-XReport Type:Expedited (15-DaCompany Report #US0101500 Age:8 YR Gender:Female I/FU:I

ominal Pain stipation al Haemorrhage ting 52039-3Report Type:Periodic I/FU:I	Report Source Consumer C Company Repor Report Source Consumer	Product Obetrol Adderall rt #FLUV00200001881 Product	PS SS	Manufacturer Shire Laboratories Inc	Route ORAL ORAL
stipation al Haemorrhage ting 52039-3Report Type:Periodic I/FU:I	c Company Repor Report Source	Adderall ct #FLUV00200001881	SS		
ting 2039-3Report Type:Periodic I/FU:I	Report Source	ct #FLUV00200001881			ORAL
2039-3Report Type:Periodio I/FU:I	Report Source		Role		
I/FU:I	Report Source		Role		
eased Appetite		Product	Role		
eased Appetite	Consumer			Manufacturer	Route
omnia	Consumer	Luvox (Fluvoxamine Maleate)	PS		ORAL
		Adderall (Adderall)	SS		ORAL
54115-8Report Type:Expedito I/FU:I	ed (15-DaCompany Repor	rt #WAES 01012510			
1/10-1	Report Source	Product	Polo	Manufacturer	Route
	Report Source	Product	ROIE	Manulacturer	Roule
nine Aminotransferase reased urtate	Health Professional	Zocor	PS	Merck Research Laboratories Div Merck Co Inc	ORAL
otransferase		Adderall Tablets 10			
		Mg	SS		
reased		Celebrex	С		
. Pain		Coumadin			
	transferase ased Pain	transferase ased	Pain Celebrex Coumadin	Adderall Tablets 10 Mg SS Pain Creatine bokinase Increased C	Pain Creatine Curve Curv

		686-1Report Type:Direct I/FU:I	Company Repor	t #			
Outcome	PT		Report Source	Product	Role	Manufacturer	Route
Dose Dura Other 1T BID	ation Weight	t Decreased		Adderall (10mg)	PS		
		094-2Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #US0100700			
Outcome Dose Dura	PT		Report Source	Product	Role	Manufacturer	Route
Hospitalization - 2 TABLETS		Pressure Increased	Consumer	Adderall	PS		
Initial or Prolon ONLY	ged Cardio	omyopathy	Health				
		rovascular Accident	Professional				

Freedom Of Information (FOI) Report

Date:02/15/01ISR Number: 3667095-4Report Type:Expedited (15-DaCompany Report #US0102100 Age:21 YR Gender:Male I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Duración	Myocardial Infarction	Health	Adderall	PS		
60 MG DAILY			Professional Company Representative	Thermadrine	С		
	lISR Number Gender:Fema	: 3666107-1Report Type:Direct le I/FU:I	Company Repor	t #			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat 5 MG PO QD		Asthenia		Adderall	PS		ORAL
Initial or P Required Intervention Prevent Perm Impairment/D	to	Convulsion		Carbatrol Adderall	C C		
	lISR Number Gender:Male	: 3669229-4Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #US0103400			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate:	ning	Asthma Bradycardia	Health Professional	Adderall 10	PS	Shire Laboratories Inc	
30 OR 35 MG		Cardiac Disorder					
DAILY		Convulsion		Albuterol	С		
		Respiratory Arrest		Flovent (Fluticasone	C		
		Ventricular Hypertrophy		Propionate) Inhaler Serevent (Salmeterol) Inhaler	C		
1				(Sarmeceror) innarer			

Date:02/28/ Age:		: 3671472-5Report Type:Expe Specifil/FU:I	edited (15-DaCompany Re	port #US0104000			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Durución	Death	Health Professional	Adderall 10	PS	Shire Laboratories Inc	
			Company Representative	Celexa	SS		
Date:02/28/ Age:8 YR	01ISR Number Gender:Fema	: 3671473-7Report Type:Expe le I/FU:I	edited (15-DaCompany Re	eport #US0104100			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitaliza Initial or 20MGAM,	ation -	Hepatocellular Damage	Other	Adderall 10	PS	Shire Laboratories Inc	
10MGPM							
Date:02/28/ Age:14 YR	01ISR Number Gender:Fema	: 3677404-8Report Type:Per le I/FU:I	iodic Company Re	eport #A004325			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Tachycardia	Health Professional	Zoloft	PS	Pfizer Pharmaceuticals Inc	ORAL
25.00 MG							
TOTAL:DAILY	:0						
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Freedom Of Information (FOI) Report

RAL				Adderall	SS		ORAL
ORAL							
ORAL				Neurontin	SS		ORAL
	lISR Number Gender:Male	: 3677439-5Report Type:Period I/FU:I	lic Company Rep	ort #A004700			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
	Duration						
Other	Durución	Anorexia	Consumer	Zoloft	PS	Pfizer	
50.00 MG		Confusional State	Health			Pharmaceuticals Inc	ORAL
50.00 110		Depersonalisation	Professional				
TOTAL:QID:ORA	ł	Depersonalisacion	TIOLEBRIOHAT				
		Drug Withdrawal Syndrome					
L							
		Dyskinesia		Adderall	SS		
1		Feeling Abnormal					
		Hepatitis					
1		Hepatocellular Damage					
		Mydriasis					
		Sensation Of Heaviness					
		Tachycardia					
Date:02/28/01 Age:17 YR (0	lISR Number Gender:Male	: 3679269-7Report Type:Period I/FU:I	lic Company Rep	oort #A032171			
-					_	-	
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
	Duration						
Other		Attention Deficit/Hyperactivity	Health Professional	Zoloft	PS	Pfizer Pharmaceuticals Inc	ORAL
100.00 MG			1101000101141				orain
		Disorder					
TOTAL:DAILY:C	)						
RAL							
50.00 MG				Adderall	SS		ORAL
TOTAL:DAILY:C	)						
4							

			Motrin Clindamyacin	C C		
Date:02/28/01ISR Number Age:10 YR Gender:Male	: 3683382-8Report Type:Periodi I/FU:I	ic Company Repor	:t #A008683			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Other	Amnesia Anorexia	Consumer	Zoloft	PS	Pfizer Pharmaceuticals Inc	ORAL
50.00 MG	Depersonalisation					0
TOTAL:DAILY:O	- Drug Withdrawal Syndrome					
RAL 30.00 MG	Mydriasis		Adderall	SS		ORAL
JU.UU MG TOTAL:DAILY:O	Peripheral Vascular					I
RAL	Disorder					
Age:8 YR Gender:Fema Outcome	r: 3679484-2Report Type:Periodi le I/FU:I PT	ic Company Repor Report Source	rt #7749 Product	Role	Manufacturer	Route
Dose Duration Other 36 MG 1X/ 1	Alopecia	Consumer	Concerta	PS	Alza Corp	ORAL
DAY, ORAL			Adderall	SS		
DOSE/FREQUENC			Adderaii	66		
У			Prozac	С		

RAL

Freedom Of Information (FOI) Report

Date:03/09/01ISR Number: 3677969-6Report Type:Expedited (15-DaCompany Report #S01-USA-00386-01 Age:28 YR Gender:Not Specifil/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Death	Duration	Death		Celexa	PS	Forest Laboratories	
				Adderall	SS	Inc	
Date:03/21/( Age:28 YR	)1ISR Number Gender:	: 3686984-8Report Type:Expedi I/FU:F	ted (15-DaCompany Repo	rt #US0104001			
Outcome	Dunchion	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Duration Death	Chest Pain Influenza Like Illness	Health Professional	Adderall 10	PS	Shire Laboratories Inc		
		Sudden Death	Professional	Celexa	SS	Inc	
Age: Outcome Dose Other 600 MG ONCE	Gender:Male	I/FU:I PT Suicide Attempt	Report Source Other	Product Adderall 10	Role PS	Manufacturer Shire Laboratories Inc	Route
Date:03/22/( Age:9 YR	)1ISR Number Gender:Male	: 3687974-1Report Type:Expedi I/FU:F	ted (15-DaCompany Repo	rt #US0101001			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Required Interventior 7.5 MG PO AN Prevent Perm Impairment/I	n to M 3 WK manent	Supraventricular Extrasystoles	Consumer	Adderall 10	PS	Shire Laboratories Inc	ORAL

Date:03/22/01ISR Number: 3687977-7Report Type:Expedited (15-DaCompany Report #US0101601 Age:15 YR Gender:Female I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Required Intervention 10MG AM & 5MC	to	Asthenia Crying	Health Professional	Adderall 10	PS	Shire Laboratories Inc	
Prevent Perma	-	Dysphagia	Company				
- Impairment/Da	-	Hypersensitivity Hypertonia Hypoaesthesia Nausea	Representative	Albuterol Inhaler Prn, Flovent	С		
	lISR Number: Gender:Male	: 3689436-4Report Type:Direct I/FU:I	t Company Repo	vrt #			

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalizati	on –	Tic		Adderall (5mg) (By			
Initial or Pr	olonged			Shire Richwood)	PS	Shire Richwood	ORAL
1 TAB P.O.							

BID

			FDA - Adverse	e Event Reporting Syste	em (AER	S)	
			Freedom C	Of Information (FOI) Re	eport		
Date:03/26/ Age:	01ISR Number: Gender:Male	: 3689439-XReport Type:Direct I/FU:I	Company Repor	rt #			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 10 MG	Duration	Affective Disorder		Adderall	PS		ORAL
		Aggression Convulsion Depression Irritability					
Age:12 YR	01ISR Number: Gender:Femal				_ ]		
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
5 MG DAILY	8 WK	Arthralgia Gait Disturbance	Other	Adderall	PS	Shire Laboratories Inc	
J MG DAILI	0 WIC	Osteoporosis		Fluoride Motrin	C C		
				Monthly Allergy Injection	С		
Date:04/04/ Age:8 YR	01ISR Number: Gender:Femal	: 3696955-3Report Type:Expedit le I/FU:F	ed (15-DaCompany Repor	rt #US0101501			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitaliza Initial or 1 10 MG PO		Abdominal Pain Constipation	Consumer	Adderall 10	PS	Shire Laboratories Inc	ORAL
10 MG PO		Gastrointestinal		Adderall	SS		ORAL
		Infection Rectal Haemorrhage Viral Infection Vomiting					

Date:04/05/01ISR Nu Age:15 YR Gender:1	mber: 3696953-XReport Type Male I/FU:I	e:Direct Company Re	port #			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duratio	on Hallucination		Adderall	PS		ORAL
20MG PO 8AM &	nallucination		Adderait	ΕD		UIAL
2000 10 0111 d	Headache					
12PM 10MG PO						
	Sedation					
5PM (SEE						
IMAGE)						
			Benadryl	SS		ORAL
50MG PO HS						
			Risperdal	С		
Date:04/06/01ISR Num Age: Gender:1		E:Expedited (15-DaCompany Re	port #US0108200			
Outcome Dose Duratio	PT on	Report Source	Product	Role	Manufacturer	Route
Hospitalization -	Anxiety	Health	Adderall 10	PS	Shire Laboratories	
Initial or Prolonged 180 MG DAILY		Professional			Inc	
100 NG DATHI	Nasopharyngitis		Effexor Nyquil	SS SS		

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:04/11/01ISR Number: 3703061-8Report Type:Direct Company Report # Gender:Male Age:15 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Hallucination, Visual Adderall PS ORAL 20 MG PO 8 AM Headache & 12 PM, & 10 Sedation MG PO 5 PM Benadryl SS ORAL 50 MG PO HS Risperdal С Date:04/23/01ISR Number: 3709337-2Report Type:Expedited (15-DaCompany Report #US0108201 Gender:Male I/FU:F Age: Role Manufacturer Outcome PTReport Source Product Route Dose Duration Aggression Adderall 10 PS Shire Laboratories Anxiety Inc ORAL 60MG TID Hostility Effexor Xr SS 600 MG TID 30 MON Medication Error Nyquil С Nasopharyngitis Upper Respiratory Tract Infection Date:04/24/01ISR Number: 3709353-0Report Type:Expedited (15-DaCompany Report #CI001000129 Age: Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Aggression Company Nyquil Initial or Prolonged Anxiety Representative Form/Version/Flavor Unknown PS ORAL ORAL Adderall (Dexamfetamine Sulfate, Dexamfetamine

ORAL			Saccharate,	SS		ORAL
ORAL			Effexor (Venlafaxine Hydrochloride)	SS		ORAL
Date:04/30/01ISR Number Age:14 YR Gender:Fema	: 3715945-5Report Type:Periodic le I/FU:I	.c Company Repor	't #US0019300			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 10 MG DAILY 8 WK	Psychotic Disorder		Adderall 10	PS	Shire Laboratories Inc	
Age:10 YR Gender:Male						
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 20 MG QAM 1 YR	Hypertension	Consumer	Adderall 20	PS	Shire Laboratories Inc	
Date:04/30/01ISR Number: Age:29 YR Gender:Male	: 3715951-0Report Type:Periodic I/FU:I	.c Company Repor	't #US0015200			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Psychotic Disorder	Consumer	Adderall 10	PS	Shire Laboratories Inc	
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Freedom Of Information (FOI) Report

Lithium Carbonate C

	lISR Number: Gender:Male	3715952-2Report Type:Periodic I/FU:I	c Company Repor	t #US0009400			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P 5MG QAM AND	ion -	Psychotic Disorder	Health Professional	Adderall 10	PS	Shire Laboratories Inc	
NOON				Imipramine	С		
	lISR Number: Gender:Male	3715953-4Report Type:Periodic	c Company Repor	t #US00023			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Migraine	Consumer	Adderall 20	PS	Shire Laboratories Inc	ORAL
20MG TID PO				Cardura Tenormin Prilosec Flonase	C C C C		
	lISR Number: Gender:Male	3715954-6Report Type:Periodio	c Company Repor	t #US00024			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10MG BID POI		Hallucination	Health Professional	Adderall 10	PS	Shire Laboratories Inc	

Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose	Duration							
Required		Anger	Other		Adderall 10	PS	Shire Laboratories	
Intervention	to	Chest Pain					Inc	
10MG AM, 10								
Prevent Perma	anent	Convulsion						
MG NOON								
Impairment/Da	amage	Electroencephalogram Abnormal						
		Headache						
		: 3722364-4Report Type:Direct		Company Report	t #			
Age: (	Gender:Male	I/FU:I						
Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose	Duration		Report	bourde	1100000	nore	handraddarer	nouce
Other		Aggression			Concerta 18/36 Mg			
		Condition Aggravated			Alza	PS	Alza	ORAL
CONCERTA PO								
		Hallucination, Visual			Adderral 2.5/5 Mg	SS		ORAL
ADDERRAL PO								
		Psychotic Disorder						
Date:05/18/0 Age:7.5 YR (		: 3725350-3Report Type:Direct le I/FU:I		Company Report	t #			
Outcome Life-Threate Required	ning							
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Freedom Of Information (FOI) Report

Prevent Pe	rmanent						
Impairment	/Damage						
-	-	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Liver Function Test		Adderall 50mg Shire			
		Abnormal		Pharmaceuticals	PS	Shire	
		Overdose				Pharmaceuticals	ORAL
30MG/20MG							
		Suicide Attempt					
MORNING/NO	ON	-					
ORAL							
-				Zoloft	SS		ORAL
30 MG MORN	ING						-
ORAL							
Date:05/30 Age:5 YR	/01ISR Number Gender:Male	r: 3731161-5Report Type:Ex e I/FU:I	pedited (15-DaCompany Re	port #US0112200			
Age.5 IK	Gender · Mare	5 T/FO·T					
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration		-				
Hospitaliz		Arthralgia	Health	Adderall 10	PS	Shire Laboratories	
Initial or	Prolonged	Joint Effusion	Professional			Inc	
2.5 MG DAI	LY					THC	
						Inc	
		Urticaria				Inc	
Date:05/30	/01ISR Number		medited (15-DaCompany Re	port #US0111900		Inc	
Date:05/30 Age:	/01ISR Number Gender:Male	r: 3731164-0Report Type:Ex	pedited (15-DaCompany Re	port #US0111900		Inc	
Age: Outcome	Gender:Male	r: 3731164-0Report Type:Ex	pedited (15-DaCompany Re Report Source	port #US0111900 Product	Role	Manufacturer	Route
Age: Outcome Dose		r: 3731164-0Report Type:Ex e I/FU:I PT	Report Source	Product		Manufacturer	Route
Age: Dutcome Dose Required	Gender:Male	r: 3731164-0Report Type:Ex = I/FU:I PT Bipolar Disorder	Report Source Health		Role		Route
Age: Outcome Dose Required	Gender:Male	r: 3731164-0Report Type:Ex e I/FU:I PT Bipolar Disorder Drug Abuser	Report Source	Product		Manufacturer	Route
Age: Outcome Dose Required Interventi	Gender:Male Duration on to	r: 3731164-0Report Type:Ex = I/FU:I PT Bipolar Disorder	Report Source Health	Product		Manufacturer Shire Laboratories	Route
	Gender:Male Duration on to rmanent	r: 3731164-0Report Type:Ex e I/FU:I PT Bipolar Disorder Drug Abuser	Report Source Health	Product		Manufacturer Shire Laboratories	Route

Date:05/30/01ISR Number: 3731168-8Report Type:Expedited (15-DaCompany Report #US0112700 Age:16 YR Gender:Male I/FU:I

Intervention to

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Death	Sudden Death	Health Professional	Adderall 10	PS	Shire Laboratories Inc	
		Company Representative	Zyprexa Zyprexa (Olanzapine)	SS C		
Date:05/31/01ISR Number Age: Gender:Fema	: 3731376-6Report Type:Expedit	ced (15-DaCompany Repor	t #US0112900			
Age: Gender Pella						
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 15 MG A.M. 4 YR	Chest Pain Pericarditis	Health Professional	Adderall 10	PS	Shire Laboratories Inc	
Required Intervention to Prevent Permanent Impairment/Damage	Tachycardia Wolff-Parkinson-White Syndrome		Triphasil	С		
Date:06/08/01ISR Number Age:9 YR Gender:Male	: 3736078-8Report Type:Direct I/FU:I	Company Repor	rt #			
Outcome Other	PT Abnormal Behaviour Aggression Agitation Drug Effect Decreased					
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Freedom Of Information (FOI) Report

	Irritability					
Dose Duration		Report Source	Product	Role	Manufacturer	Route
10 MG BID			Adderall 10 Mg	PS		ORAL
ORAL						
Date:06/08/01ISR Numb Age:28 YR Gender:Ma	er: 3736616-5Report Type:Expe le I/FU:I	dited (15-DaCompany Repo	ort #HQ9408306APR2001			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 100 MG 3X PER	Accidental Overdose Aggression	Health Professional	Effexor	PS	Wyeth Ayerst Laboratories	ORAL
Other 1 DAY ORAL	Anxiety					
			Adderall (Amfetamine Aspartate/Amfetamine Sulfate/Dexamfetamin			
			e Saccharate/Dexamfeta	SS		ORAL
60 MG 3X PER						
1 DAY ORAL			Nyquil (Dextromethorphan Hydrobromide/Doxylam ine			
8 CAPSULES			Succinate/Ephedrine	SS		ORAL
ACCIDENTAL						
OVERDOSE ORAL						
Date:06/15/01ISR Numb Age:29 YR Gender:Ma	er: 3740256-1Report Type:Expe le I/FU:F	dited (15-DaCompany Repo	ort #C1001000129			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route

Hospitalization - Initial or Prolonged	Aggression Anger Anxiety	Company Representative	Nyquil, Form Version/Flavor Unknown	PS	ORAL
1 LIQUICAP					
EIGHT TIMES					
DAILY, ORAL					
			Adderall (Dexamfetamine		
			Sulfate, Dexamfentamine		
			Saccharate,	SS	ORAL
60 MILLIGRAMS					
THREE TIMES					
DAILY, ORAL					
			Effexor(Venlafaxine Hydrochloride)	SS	ORAL
100					
MILLIGRAMS					
THREE TIMES					
DAILY, ORAL					
Date:06/18/01ISR Numbe Age:11 YR Gender:Mal		xpedited (15-DaCompany Rep	ort #US0110701		
Outcome	PT				
Required Intervention to	Abnormal Behaviour Anger				
Prevent Permanent Impairment/Damage	Chest Pain Convulsion				
Imparrment/Damaye	Electroencephalogram				
1					

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Abnormal Headache Report Source Product Role Manufacturer Route Duration Dose Other Adderall 10 PS Shire Laboratories Inc 10 MG AM, 10 MG NOON Date:06/18/01ISR Number: 3741541-XReport Type:Expedited (15-DaCompany Report #US0113800 Age:10 YR Gender:Male I/FU:I PTRole Manufacturer Outcome Report Source Product Route Dose Duration Shire Laboratories Epilepsy Other Adderall 10 PS Required Intervention to Inc AM & LUNCH Prevent Permanent Impairment/Damage Date:06/20/01ISR Number: 3743528-XReport Type:Direct Company Report # Gender:Female Age:7 YR I/FU:I Role Manufacturer PTReport Source Product Outcome Route Dose Duration Hospitalization -Drug Level Above Depakote PS 1000MG Initial or Prolonged Therapeutic Adderal Discontinued Lethargy (?) SS Vomiting Date:06/29/01ISR Number: 3750215-0Report Type:Direct Company Report # Age:13 YR Gender:Male I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Required Central Nervous System Adderall PSORAL 5MG P.O. Intervention to Stimulation DAILY

Prevent Permanent Impairment/Damage

Date:07/04/01ISR Number Age:13 YR Gender:Male	: 3751981-0Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #US0115300			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Convulsion	Health Professional	Adderall 10	PS	Shire Pharmaceutical Development Inc	
		Company Representative	Zoloft (Sertraline)	С		
Date:07/04/01ISR Number Age:13 YR Gender:Male	: 3751984-6Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #US0115100			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 30 MG DAILY 3 YR	Bone Marrow Depression Ecchymosis	Health Professional	Adderall 10	PS	Shire Pharmaceutical Development Inc	
SUMB DATE S TR	Pancytopenia		Occasional Aspirin	С		

Freedom Of Information (FOI) Report

Date:07/06/01ISR Number: 3753892-3Report Type:Expedited (15-DaCompany Report #US0115800 Age:16 YR Gender:Male I/FU:I

> Injury Insomnia

Outcome Dose	Duratio	PT	Report Source	Product	Role	Manufacturer	Route
Death	Duracio	Hepatic Steatosis Sudden Death	Health Professional	Adderall 10	PS	Shire Pharmaceutical Development Inc	
20 MG BID	2 7	YR				-	
5 MG QD	2	YR	Company	Zyprexa	SS		I
	4	IN	Representative	Zyprexa	С		
Date:07/11/( Age:	)1ISR Numl Gender:Ma		Type:Expedited (15-DaCompany Rej	port #US0116100			
Outcome	Duratio	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration	n Leukopenia	Health Professional	Adderall 10	PS	Shire Laboratories Inc		
Age:5 YR Outcome Dose Hospitalizat	Gender:Ma Duration	PT	Report Source Health	Product Adderall 10	Role		Route
Dose Hospitalizat Initial or B	cion - Prolonged	n Arthritis	Health Professional	Adderall 10	PS	Shire Laboratories Inc	Rouce
2.5 MG DAILY Date:07/16/0 Age:5 YR Outcome			Type:Expedited (15-DaCompany Rep Report Source	port #US0116700 Product	Role	Manufacturer	Route
Dose	Duration		-				
Hospitalizat Initial or H		Aggression Bite	Other	Adderall 10	PS	Shire Laboratories Inc	
25 MG DAILY		BILE				Inc	
		Dysphonia Hostility		Tegretol (Carbamazepine)	С		

Date:07/17/01ISR Number: 3759993-8Report Type:Direct Company Report # Age:12 YR Gender:Male I/FU:I Outcome  $\mathbf{PT}$ Report Source Product Role Manufacturer Route Duration Dose Life-Threatening Aggression Adderall 30 Mg PSORAL 30 MG/ TWICE Hospitalization -Alopecia DAILY/ ORAL Initial or Prolonged Amnesia Zyprexia/ 5 Mg SS ORAL 5 MG/ Disability Delusion BEDTIME/ ORAL Insomnia Paranoia Psychotic Disorder Pyromania Suicidal Ideation

Date:08/03/01ISR Number: 3771545-2Report Type:Expedited (15-DaCompany Report #US0117200 Age:21 YR Gender:Female I/FU:I

Thinking Abnormal Weight Decreased

Outcome		РТ	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Ecchymosis Prothrombin Time	Health Professional	Adderall 10	PS	Shire Laboratories Inc	
SEE NARRATIVE	E	Prolonged		Birth Control Pills	С		

Freedom Of Information (FOI) Report

Date:08/13/01ISR Number: 3776399-6Report Type:Expedited (15-DaCompany Report #US0118900 Age: Gender:Male I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Myocardial Infarction	Health Professional	Adderall 10	PS	Shire Laboratories Inc	

Date:08/14/01ISR Number: 3777501-2Report Type:Expedited (15-DaCompany Report #US0119300 Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration	1 1	Report Bource	110ddet	ROIC	Manufacturer	Rouce
Hospitalization -	Agitation	Other	Adderall 10	PS	Shire Laboratories	
Initial or Prolonged SEE NARRATIVE	Cyanosis				Inc	
	Diarrhoea		Flovent	С		
	Disorientation					
	Dizziness					
	Drug Abuser					
	Fall					
	Mania					
	Pallor					
	Panic Disorder Without					
	Agoraphobia Sedation					
	Stupor					
	Syncope					
	Бунсоре					
Date:08/15/01ISR Numbe	er: 3778497-XReport Type:Expedi	ted (15-DaCompany Repo	rt #US0119000			
Age:8 YR Gender:Mal						
Outcome .	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Priapism	Health Professional	Adderall 10	PS	Shire Laboratories Inc	

Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Death		Arrhythmia	Health	Adderall	PS	
20 MG ONE						
		Cardiomegaly	Professional			
TIME ONLY						
		Circulatory Collapse Fatigue Heart Rate Decreased Hypertrophic Obstructive Cardiomyopathy Sudden Death	Company Representative			
	01ISR Number Gender:Male	: 3783319-7Report Type:Exped	ited (15-DaCompany Re	eport #US0120200		
			lited (15-DaCompany Re Report Source	port #US0120200 Product	Role Manufacturer	Route
Age:35 YR		e I/FU:I			Role Manufacturer	Route
Age:35 YR Outcome	Gender:Male	e I/FU:I			Role Manufacturer PS	Route
Age:35 YR Outcome Dose Life-Threate	Gender:Male Duration ening	e I/FU:I PT	Report Source	Product		Route

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:08/31/01ISR Number: 3786839-4Report Type:Expedited (15-DaCompany Report #US0121200 Aqe:16 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Hospitalization -Health Adderall PS Syncope 10 MG DAILY Initial or Prolonged Professional Date:08/31/01ISR Number: 3787034-5Report Type:Expedited (15-DaCompany Report #US0117201 Age:21 YR Gender:Female I/FU:F Outcome ΡТ Report Source Product Role Manufacturer Route Dose Duration Prothrombin Time Adderall Other Health PS SEE NARRATIVE Prolonged Professional Birth Control Pills С Date:08/31/01ISR Number: 3787042-4Report Type:Expedited (15-DaCompany Report #US0118901 Age:54 YR Gender:Male I/FU:F Role Manufacturer Outcome PTReport Source Product Route Dose Duration Life-Threatening Myocardial Infarction Adderall ORAL Health PS20 MG BID PO Hospitalization -Professional Stress Initial or Prolonged Date:08/31/01ISR Number: 3787074-6Report Type:Expedited (15-DaCompany Report #US0120800 Age:12 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Hepatic Function Abnormal Health Adderall PS Initial or Prolonged Liver Function Test Professional Abnormal

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Death 30 MG DAILY	Duración	Circulatory Collapse	Health	Adderall	PS		
		Convulsion Heart Rate Increased Heat Exhaustion Heat Stroke	Professional	Depakote (Divalproex Sodium)	С		
	lISR Number Gender:Male	: 3789506-6Report Type:Exp I/FU:I	edited (15-DaCompany Re	eport #US0121600			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Death 10 MG BID	Duración	Drug Level Above	Health	Adderall	PS		
		Therapeutic Drug Toxicity	Professional Other	Insulin	C		
	lISR Number Gender:Male	PT Agitation Anger	edited (15-DaCompany Re	eport #US008899			
		Delusion Diarrhoea					
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Freedom Of Information (FOI) Report

		Emotional Disorder Fatigue Feeling Abnormal	Report Source	Product	Role Manufacturer	Route
Dose	Duration	Hallucination, Auditory	Health	Provigil	PS	ORAL
200 MG QD				110.1911	10	0141_
ORAL		Laceration	Professional			
100 MG QD		Overdose		Provigil	SS	ORAL
		Psychotic Disorder				
ORAL				Provigil	SS	ORAL
200 MG QD				FIOVIGII	66	UIVEL
ORAL						
20 MG TID				Adderall	SS	ORAL
ORAL				Depakote	С	
				Celexa	C	
Age:11 YR Outcome	Gender:Male	r: 3795206-9Report Type:Expedi e I/FU:F PT	ited (15-DaCompany Repo Report Source		C Role Manufacturer	Route
Age:11 YR Outcome Dose Hospitalizat	Gender:Male	e I/FU:F		ort #US0120801		Route
Age:11 YR Outcome Dose	Gender:Male Duration tion -	e I/FU:F PT	Report Source	ort #US0120801 Product	Role Manufacturer	Route

	ted (15-DaCompany Repo	rt #US0122300			
PT	Report Source	Product	Role Manufact	curer	Route
Decreased Appetite	Other	Adderall	PS		
Grand Mal Convulsion Insomnia Partial Seizures Petit Mal Epilepsy Sedation					
: 3797823-9Report Type:Expedi I/FU:F	ted (15-DaCompany Repo	rt #US0115101			
PT	Report Source	Product	Role Manufact	curer	Route
Aplastic Anaemia	Health	Adderall	PS		
Bone Marrow Transplant Chemical Injury Pancytopenia	Professional				
: 3797930-0Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	rt #M0575-2001			
PT					
Alanine Aminotransferase Increased Aspartate					
	<pre>le I/FU:I PT Decreased Appetite Grand Mal Convulsion Insomnia Partial Seizures Petit Mal Epilepsy Sedation : 3797823-9Report Type:Expedi I/FU:F PT Aplastic Anaemia Bone Marrow Transplant Chemical Injury Pancytopenia : 3797930-OReport Type:Expedi I/FU:I PT Alanine Aminotransferase Increased</pre>	Le I/FU:I PT Report Source Decreased Appetite Other Grand Mal Convulsion Insomnia Partial Seizures Petit Mal Epilepsy Sedation 3797823-9Report Type:Expedited (15-DaCompany Report I/FU:F PT Report Source Aplastic Anaemia Health Bone Marrow Transplant Professional Chemical Injury Pancytopenia 3797930-OReport Type:Expedited (15-DaCompany Report I/FU:I PT Alanine Aminotransferase Increased	PTReport SourceProductDecreased AppetiteOtherAdderallGrand Mal Convulsion Insomnia Partial Seizures Petit Mal Epilepsy sedationState State	le I/FU:I Report Source Product Role Manufact PT Report Source Product Role Manufact Decreased Appetite Other Adderall PS Grand Mal Convulsion Insomnia Partial Seizures Petit Mal Epilepsy Sedation 3797823-9Report Type:Expedited (15-DaCompany Report #USO115101 I/FU:F PT Report Source Product Role Manufact Aplastic Anaemia Health Adderall PS Bone Marrow Transplant Professional Chemical Injury Pancytopenia 3797930-OReport Type:Expedited (15-DaCompany Report #M0575-2001 I/FU:I PT Alanine Aminotransferase Increased	Le     I/FU:I       PT     Report Source     Product     Role Manufacturer       Decreased Appetite     Other     Adderall     PS       Grand Mal Convulsion     Insommia     Partial Seizures     Pertit Mal Spilepsy       Partial Seizures     Pertit Mal Epilepsy     Sedation       : 3797823-9Report Type:Expedited (15-DaCompany Report #US0115101     I/FU:F       PT     Report Source     Product       Aplastic Anaemia     Health     Adderall       Bone Marrow Transplant     Professional       Chemical Injury     Pancytopenia

Freedom Of Information (FOI) Report

Dose 15 MG QHS PC 20 MG BID	Duration	Aminotransferase Increased Jaundice Nausea Pharyngolaryngeal Pain Pyrexia Vomiting	Report Source Health Professional Other	Product Remeron Adderall	Role PS SS	Manufacturer Organon Inc.	Route ORAL
	)1ISR Number Gender:Male	: 3798406-7Report Type:Expedi I/FU:I	ited (15-DaCompany Repo	ort #US0122600			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Aggression Hostility	Health Professional Company Representative	Adderall Tenex	PS C		
Date:09/28/( Age:	)1ISR Number Gender:Fema	: 3801745-4Report Type:Expedi le I/FU:I	ited (15-DaCompany Repo	ort #US0124200			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Post Procedural Haemorrhage	Health Professional	Adderall	PS		
	)1ISR Number Gender:Male	: 3802070-8Report Type:Expedi I/FU:F	ited (15-DaCompany Repo	ort #US_01-153-01			
Outcome	5	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Aggression		Adderall	PS		
10 MG 1 TIME	2	Grand Mal Convulsion Subarachnoid Haemorrhage		Zoloft (Sertraline)	С		

Date:10/03/01ISR Age:8.5 YR Gend		3804530-2Report Type:Expedite	ed (15-DaCompany Report	t #US-01-234-00			
Outcome Dose Dur	Fation	т	Report Source	Product	Role	Manufacturer	Route
		phasia		Adderall	PS		
7.5 MG BID	L G M	Difficulty In Walking Wait Disturbance Muscular Weakness Myasthenic Syndrome					
	Number: ler:Male	3806771-7Report Type:Expedite I/FU:I	ed (15-DaCompany Report	t #US0124100			
Outcome Dose Dur	Fation	Т	Report Source	Product	Role	Manufacturer	Route
Other		Convulsion	Health Professional	Adderall	PS		
Date:10/05/01ISR Age:13 YR Gend		3806827-9Report Type:Expedite	ed (15-DaCompany Report	z #A122746			
Outcome Dose Dur	Fation	Т	Report Source	Product	Role	Manufacturer	Route
Hospitalization 20.00 MG		ggression	Health	Zoloft Tablets	PS		
Initial or Prolo TOTAL	onged G	rand Mal Convulsion	Professional				
100.00 MG	5	ubarachnoid Haemorrhage		Adderall	SS		
22-Aug-2005 10: Page: 62	34 AM						

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Freedom Of Information (FOI) Report

TOTAL

Date:10/10 Age:31 YR	/01ISR Number Gender:Male	r: 3808260-2Report Type:Expec e I/FU:I	dited (15-DaCompany Re	eport #US0124900			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Accident	Health	Provigil	PS		
		Agitation	Professional	Adderall	SS		
20 MG TID		Delusion		Depakote (Divalproex			
1		Delusional Perception		Sodium)	С		
		Depersonalisation		Celexa (Citalopram)	C		
		Diarrhoea			U		
		Emotional Disorder					
		Feeling Abnormal					
		Hallucination					
		Hallucination, Auditory					
		Laceration					
		Overdose					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Aggression	Health	Adderall	PS		
		Hostility Screaming	Professional	Tenex (Guanfacine)	C		
	/01ISR Number Gender:Fema	r: 3808267-5Report Type:Expec ale I/FU:F	dited (15-DaCompany Re	eport #US0122301			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Retire Discoult:	Others	N delesse ] ]	DC		
Other 5 UP TO 15	MC	Eating Disorder	Other	Adderall	PS		
5 04 10 15		Grand Mal Convulsion					
		Partial Seizures					
		Petit Mal Epilepsy					
		Sedation					
A							

Date:10/17/ Age:7 YR	01ISR Number Gender:Male		e:Expedited (15-DaCompany Rej	port #US0125300		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Death	Durución	Arrhythmia Sudden Death	Health Professional	Adderall	PS	
	01ISR Number Gender:Male	: 3816806-3Report Typ I/FU:I	e:Periodic Company Re	port #US008798		
Outcome	Derestian	PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration	Insomnia	Health	Provigil	PS	ORAL
50 MG QD OR	AL		Professional	Provigil	SS	ORAL
200 MG QD						
ORAL				Adderall	SS	ORAL
15 MG BID						
ORAL;						
DURATION: A						
FEW YEARS				Atenolol	С	
22-Aug-2005	10:34 AM					

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			erse Event Reporting Sy om Of Information (FOI		)	
				,		
Date:10/26/01ISR Nu Age: Gender:	amber: 3816428-4Report Type Male I/FU:I	:Direct Company Re	eport #			
Outcome Dose Durati 20 MG Q AM	PT ion Sleep Disorder	Report Source	Product Adderall	Role PS	Manufacturer	Route
20 MG Q AM						
Date:10/30/01ISR Nu Age: Gender:	umber: 3817356-0Report Type Male I/FU:I	:Direct Company Re	eport #			
Outcome	PT	Report Source	Product	Role 1	Manufacturer	Route
Dose Durati Life-Threatening Hospitalization - 80MG PER Initial or Prolonge	Cardiomyopathy Medication Error		Adderall 20mg Shire	PS	Shire	
Disability Required Intervention to Prevent Permanent Impairment/Damage	eu					
Date:10/31/01ISR Nu Age: Gender:	umber: 3818606-7Report Type Male I/FU:I	Expedited (15-DaCompany Re	eport #US0127600			
Outcome	PT	Report Source	Product	Role 1	Manufacturer	Route
Dose Durat: Hospitalization - SEE NARRATIVE	Pneumonia Mycoplasmal		Adderall	PS		
Initial or Prolonge	ed	Professional				
Date:10/31/01ISR Nu Age:10 YR Gender:	umber: 3818607-9Report Type Male I/FU:I	Expedited (15-DaCompany Re	eport #US0127000			
Outcome Dose Durati	PT	Report Source	Product	Role 1	Manufacturer	Route
Dose Durat. Death SEE NARRATIVE	Circulatory Collapse	Health	Adderall	PS		
	Sudden Death	Professional Company				

## Representative

Date:11/02/0 Age:	01ISR Number: Gender:Male	3819834-7Report Type:Direct I/FU:I	C	ompany Report	#			
Outcome Dose	Duration	PT	Report So	urce	Product	Role	Manufacturer	Route
Other 5MG BID PO		Abnormal Behaviour			Adderall (Tabs 5m	mg) PS		ORAL
		Decreased Appetite Drug Abuser Insomnia Tic						
Date:11/06/0 Age:	01ISR Number: Gender:Femal	3821632-5Report Type:Expedite e I/FU:I	ed (15-DaCo	ompany Report	#US0127400			
Outcome Dose	Duration	РТ	Report So	urce	Product	Role	Manufacturer	Route
Other 2.5MG ONE		Dyspnoea	Health	1	Adderall	PS		
TIME			Profession	nal				

			FDA – Adve	erse Event Reporting Syst	tem (AER	2S)	
			Freedo	om Of Information (FOI) H	Report		
	01ISR Number Gender:Male	: 3821633-7Report Type:Exp I/FU:I	pedited (15-DaCompany Re	≥port #US0127500			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitaliza SEE NARRATI	ation -	Fatigue	Consumer	Adderall	PS		
Initial or		Myocardial Infarction		Vioxx (Rofecoxib)	С		
	01ISR Number Gender:Male	: 3825111-0Report Type:Exp I/FU:I	pedited (15-DaCompany Re	≥port #US0128400			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10 MG BID	Duración	Blood Alkaline	Health	Adderall	PS		
10 MU 710		Phosphatase Increased Blood Cholesterol Increased	Professional	Risperdal (Risperidone)	С		
Date:11/14/ Age:2 YR	01ISR Number Gender:Male	: 3825113-4Report Type:Exp I/FU:I	pedited (15-DaCompany Re	≥port #US0127900			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 20MG ONE TI		Agitation	Health	Adderall	PS		
ZUMG ONE II	ME.	Medication Error Overdose	Professional				
Date:11/19/ Age:16 YR	01ISR Number Gender:Fema	: 3827009-0Report Type:Exp le I/FU:I	pedited (15-DaCompany Re	≥port #US0128500			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Required 20 MG QD Interventio: Prevent Peri Impairment/:	manent	Hypersensitivity	Other	Adderall	PS		

Date:11/19/01ISR Number Age:21 YR Gender:Fema	: 3827536-6Report Type:Direct le I/FU:I	Company Repor	t #		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Life-Threatening 10MG X 2	Paranoia		Adderall	PS	
Hospitalization - DAILY 3 WK Initial or Prolonged	Psychotic Disorder				
Date:11/20/01ISR Number Age:11 YR Gender:Male	: 3827975-3Report Type:Expedit E I/FU:I	ed (15-DaCompany Repor	t #US0129300		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 10 MG DAILY	Optic Neuritis	Health	Adderall	PS	
		Professional			
Date:11/20/01ISR Number Age: Gender:Male	: 3828266-7Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #US0128800		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - SEE NARRATIVE	Drug Abuser	Health	Adderall	PS	
Initial or Prolonged	Drug Dependence Paranoia Psychotic Disorder	Professional			
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FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:11/27/01ISR Number: 3830744-1Report Type:Expedited (15-DaCompany Report #US0100200 Gender:Male Aqe:11 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Difficulty In Walking Health Adderall Xr PS 30 MG Gait Disturbance Professional Flovent Inhaler С Hypertonia Ddavp (Desmopressin Muscle Spasms Acetate) С Date:11/27/01ISR Number: 3830745-3Report Type:Expedited (15-DaCompany Report #US0129100 Age:5 YR Gender: Female I/FU:I Role Manufacturer Outcome ΡТ Report Source Product Route Duration Dose Adderall Aggression Other PS Other 5 M UP TO 15 Hostility MG QD "Allergy Medication" C Date:11/29/01ISR Number: 3832762-6Report Type:Expedited (15-DaCompany Report #US0129600 Age:12 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Abdominal Distension Health Adderall PS 10 MG OD Initial or Prolonged Gastrointestinal Necrosis Professional Intestinal Ischaemia Company Intestinal Obstruction Representative Date:12/04/01ISR Number: 3846173-0Report Type:Direct Company Report #USP 54661 Age:12 YR Gender:Male I/FU:I PTReport Source Product Role Manufacturer Route Outcome Dose Duration Abnormal Behaviour Adderall(Dextroamphe Other Medication Error tamine Sulfate, Dextroamphetamine

	Saccharate, Amphetamine				
TABLET	Adderall(Dextroamphe tamine Sulfate, Dextroamphetamine Saccharate, Amphetamine	SS	Shire		

## TABLET

Date:12/05/01ISR Nu Age:10 YR Gender:	umber: 3834906-9Report Type:Exp Female I/FU:F	pedited (15-DaCompany R	eport #US0122302		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Durati Other 5 UP TO 15 MG	Grand Mal Convulsion	Consumer	Adderall	PS	
15 MG AM	Partial Seizures	Other	Adderall	SS	
10 110 111	Petit Mal Epilepsy		Depakote Er (Divalproex Sodium)	C	

Date:12/05/01ISR Number: 3834907-0Report Type:Expedited (15-DaCompany Report #US0130100 Age:17 YR Gender:Female I/FU:I

Outcome	 PT	Report Source	Product	Role Manufacturer	Route
Dose Hospitalizati SEE NARRATIVE	Drug Level Decreased	Health	Adderall	PS	
Initial or Pr	Epilepsy	Professional	Tegretol (Carbamazepine)	C	

Freedom Of Information (FOI) Report

Carbatrol (Carbamazepine) C Topamax (Topiramate) C

Date:12/05/01ISR Number: 3834927-6Report Type:Expedited (15-DaCompany Report #US0100400 Gender:Female Age: I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Adderall Xr Other Arrhythmia Health PS 40 MG Professional Date:12/10/01ISR Number: 3838254-2Report Type:Direct Company Report # Age:12 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Death Adderall 30 Mg PS ORAL Anger MORNING ORAL Completed Suicide Depression Dysphemia Social Avoidant Behaviour Speech Disorder Tic Date:12/17/01ISR Number: 3840260-9Report Type:Expedited (15-DaCompany Report #US0128501 Age:17 YR Gender:Female I/FU:I PTRole Manufacturer Outcome Report Source Product Route Duration Dose Required Blood Potassium Decreased Consumer Adderall PS 20 MG QID Intervention to Blood Triglycerides Other Prevent Permanent Decreased Impairment/Damage Heart Rate Irregular Muscle Rigidity Peripheral Coldness Pulse Absent Respiratory Distress

		Expedited (15-DaCompany Re	eport #US0101200		
Duration	PT	Report Source	Product	Role Manufacturer	Route
Duración	Convulsion	Health	Adderall Xr	PS	
		Professional			
		Expedited (15-DaCompany Re	eport #US0101400		
	PT	Report Source	Product	Role Manufacturer	Route
	Hallugination	Othor	Addorall Vr	DQ	
	nallucination	other	Adderall Xr	P5	
	Gender:Male Duration DIISR Number	Gender:Male I/FU:I PT Duration OllISR Number: 3840844-8Report Type Gender:Male I/FU:I PT Duration tion - Hallucination Gender:Male	Gender:Male       I/FU:I         PT       Report Source         Duration       Health         Convulsion       Health         Professional         Olisk Number:       3840844-8Report Type:Expedited (15-DaCompany Regender:Male         I/FU:I         PT       Report Source         Duration       PT         Convulsion       Report Source         Ouration       Hallucination         Other       Other	PT     Report Source     Product       Duration     Health     Adderall Xr       Convulsion     Health     Professional       PIISR Number:     3840844-8Report Type:Expedited (15-DaCompany Report #US0101400       Cender:Male     I/FU:I       PT     Report Source       PT     Report Source       PT     Report Source       PT     Adderall Xr	Gender:Male       I/FU:I         PT       Report Source       Product       Role Manufacturer         Duration       Health       Adderall Xr       PS         Convulsion       Health       Adderall Xr       PS         Professional       Professional       Professional         DIISR Number:       3840844-8Report Type:Expedited (15-DaCompany Report #US0101400       Role Manufacturer         OTISR Number:       PT       Report Source       Product         Puration       PT       Report Source       Product         Duration       Other       Adderall Xr       PS

			FDA – Adv	erse Event Reporting Sys	tem (AEF	RS)	
			Freed	om Of Information (FOI)	Report		
	)1ISR Number Gender:Male		Expedited (15-DaCompany R	eport #US0129000			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10MG 2X/DAY		Scleroderma	Health	Adderall	PS		
TOMG ZA/DAT		Skin Depigmentation Skin Ulcer Vitiligo	Professional				
	)2ISR Number Gender:Male	r: 3852761-8Report Type e I/FU:I	Direct Company R	eport #CTU 159102			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Life-Threate 20MG BID	Duration ening	Fall		Adderall 20mg Bid	PS		
Hospitalizat Initial or H Disability		Mania Psychotic Disorder					
Date:01/22/( Age:13 YR		r: 3856931-4Report Type e I/FU:I	:Direct Company R	eport #CTU 159748			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Aggression Agitation		Adderall Xl (20mg Daily)	PS		
20MG DAILY		Disturbance In Social Behaviour		Imipramine	С		
	)2ISR Number Gender:Male	r: 3859663-1Report Type e I/FU:I	Direct Company R	eport #CTU 159910			
Outcome	- · · ·	PT	Report Source	Product	Role	Manufacturer	Route
Dose Life-Threate Hospitalizat 100MG DAY	-	Convulsion Stevens-Johnson Syndr	rome	Carbamazepine (100mg) Tab Teva	PS	Teva	ORAL

Initial or Prol	longed	Viral Infection					
ORAL Required Intervention to 20MG DAY ORAL	o			Adderall 20mg Tab Rich	SS	Rich	ORAL
Prevent Permane Impairment/Dama				Mebendazole	С		
	SR Number: nder:Male	: 3859036-1Report Type:Expedit I/FU:F	ed (15-DaCompany Report	t #US0120601			
Outcome Dose Du	uration	PT	Report Source	Product	Role	Manufacturer	Route
Death 20 MG ONE		Arrhythmia	Health	Adderall	PS		
		Cardiomegaly	Professional				

TIME ONLY

Circulatory Collapse Fatigue Hypertrophic Obstructive Cardiomyopathy Pulse Absent Sudden Death

Freedom Of Information (FOI) Report

Date:01/24/02ISR Number: 3859046-4Report Type:Expedited (15-DaCompany Report #US0201700 Age:9 YR Gender:Male I/FU:I

Dunie tiere	PT	Report Source	Product	Role Manufacturer	Route
Duration	Chest Pain	Consumer	Adderall Xr	PS	
	Headache	Other	Adderall Xr	SS	
	Medication Error		Clonidine Wellbutrin	С	
			(Bupropion)	C	
	Duration	Duration Chest Pain Headache	Duration Chest Pain Headache Other	Duration     Chest Pain     Consumer     Adderall Xr       Headache     Other     Adderall Xr       Medication Error     Clonidine Wellbutrin	Duration     Chest Pain     Consumer     Adderall Xr     PS       Headache     Other     Adderall Xr     SS       Medication Error     Clonidine Wellbutrin     C

Date:01/24/02ISR Number: 3859453-XReport Type:Expedited (15-DaCompany Report #US0201500 Age:10 YR Gender:Male I/FU:I

Outcome Dose Other 30 MG DAILY		PT	Report Source	Product	Role Manufacturer	Route
	Duration	Aggression	Other	Adderall Xr	PS	
		Attention Deficit/Hyperactivity Disorder Condition Aggravated Hostility Hypersensitivity				

Date:01/28/02ISR Number: 3862083-7Report Type:Expedited (15-DaCompany Report #US0201600 Age:10 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Other		Arrhythmia Cardiac Disorder Contusion Electrocardiogram Qt Interval Road Traffic Accident	Health Professional	Adderall	PS	

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - 20 MG	Abdominal Pain	Health	Adderall	PS	
Initial or Prolonged	Agitation Dyspnoea Vomiting	Professional			
Date:02/04/02ISR Numbe Age:12 YR Gender:Mal Outcome	er: 3865010-1Report Type:Exp .e I/FU:F PT	edited (15-DaCompany Re Report Source	eport #US0129301 Product	Role Manufacturer	Route
Age:12 YR Gender:Mal	.e I/FU:F		-	Role Manufacturer	Route
Age:12 YR Gender:Mal Outcome	.e I/FU:F		-	Role Manufacturer PS	Route

Outcome PT Report Source Product Role Manufacturer Dose Duration Hospitalization - Abdominal Distension Health Adderall PS Initial or Prolonged Gastrointestinal Necrosis Intestinal Obstruction Vasculitis Date:02/05/02ISR Number: 3865299-9Report Type:Direct Company Report #CTU 160919 Age: Gender: I/FU:I Outcome PT Report Source Product Role Manufacturer Dose Duration Other Medication Error Health Adderall Xr Professional 10,20,30mg Shire PS Shire 30MG 2 PER DAY: 20MG 2 PER DAY Date:02/11/02ISR Number: 3869110-1Report Type:Expedited (15-DaCompany Report #US0203100 Age: Gender:Male I/FU:I Outcome PT Report Source Product Role Manufacturer		.S )	tem (AER	e Event Reporting Sys	FDA - Advers			
Age:12 YR       Gender:Male       I/FU:F       Report Source       Product       Role       Manufacturer         Outcome       Duration       Hoominal Distension       Health       Adderall       Ps         Hospitalization -       Abdominal Distension       Health       Adderall       Ps         10       MG QD       Gastrointestinal Necrosis       Professional       Ps         Initial or Prolonged       Gastrointestinal Necrosis       Professional       Nacculitis         Date:02/05/02ISR Number:       3865299-9Report Type:Direct       Company Report #CTU 160919         Age:       Gender:       I/FU:I       Company Report #CTU 160919         Age:       I/FU:I       Report Source       Product       Role         Outcome       PT       Report Source       Product       Role         Outcome       PT       Report Source       Product       Role         30MG 2 PER       Medication Error       Health       Adderall Xr       Professional       10,20,30mg Shire       PS       Shire         Daty: 20MG 2       PER       DAY       Pact:02/11/02ISR Number:       3869110-1Report Type:Expedited (15-DaCompany Report #US0203100       Houmage:			Report	Of Information (FOI)	Freedom			
Dose     Duration       Hospitalization -     Abdominal Distension     Health     Adderall     PS       Initial or Prolonged     Gastrointestinal Necrosis Intestinal Obstruction     Professional     Professional       Date:02/05/02ISR Number:     3865299-9Report Type:Direct Gender:     Company Report #CTU 160919       Age:     Gender:     I/FU:I       Outcome     PT     Report Source     Professional       Obse     Duration     Medication Error     Health     Adderall Xr       Pofessional     10,20,30mg Shire     PS     Shire       30MG 2 PER     PER DAY     Pate:02/11/02ISR Number:     3869110-1Report Type:Expedited (15-DaCompany Report #US0203100       Age:     Gender:Male     I/FU:I     Gender: Manufacturer				rt #US0129601	ed (15-DaCompany Repo			
Hospitalization - Abdominal Distension Health Adderall PS 10 MG QD Initial or Prolonged Gastrointestinal Necrosis Intestinal Obstruction Vasculitis Date:02/05/02ISR Number: 3865299-9Report Type:Direct Company Report #CTU 160919 Age: Gender: I/FU:I Outcome Duration Other PT Report Source Product Role Manufacturer Dote: Duration Other Medication Error Health Adderall Xr Professional 10,20,30mg Shire PS Shire 30MG 2 PER DAY; 20MG 2 PER DAY Date:02/11/02ISR Number: 3869110-1Report Type:Expedited (15-DaCompany Report #US0203100 Age: Gender:Male I/FU:I Outcome PT Report Source Product Role Manufacturer	Route	Manufacturer	Role	Product	Report Source	PT		
Initial or Prolonged Gastrointestinal Necrosis Intestinal Obstruction Vasculitis Date:02/05/02ISR Number: 3865299-9Report Type:Direct Company Report #CTU 160919 Age: Gender: I/FU:I Outcome PT Report Source Product Role Manufacturer Dose Duration Other Medication Error Health Adderall Xr Professional 10,20,30mg Shire PS Shire 30MG 2 PER DAY; 20MG 2 PER DAY Date:02/11/02ISR Number: 3869110-1Report Type:Expedited (15-DaCompany Report #US0203100 Age: Gender:Male I/FU:I Outcome PT Report Source Product Role Manufacturer			PS	Adderall	Health	Abdominal Distension		Hospitalizat
Age:       Gender:       I/FU:I         Outcome       PT       Report Source       Product       Role Manufacturer         Dose       Duration       Medication Error       Health       Adderall Xr         Other       Medication Error       Health       Adderall Xr         Pofessional       10,20,30mg Shire       PS       Shire         DAY; 20MG 2       PER       Per DAY       Value       Value         Date:02/11/02ISR Number:       3869110-1Report Type:Expedited (15-DaCompany Report #US0203100       Value       Fully in the state of the stat					Professional	Intestinal Obstruction	]	
Dose Duration Other Medication Error Health Adderall Xr Professional 10,20,30mg Shire PS Shire 30MG 2 PER DAY; 20MG 2 PER DAY Pate:02/11/02ISR Number: 3869110-1Report Type:Expedited (15-DaCompany Report #US0203100 Age: Gender:Male I/FU:I Outcome PT Report Source Product Role Manufacturer				rt #CTU 160919	Company Repo			
Other     Medication Error     Health     Adderall Xr       JOMG 2 PER     Professional     10,20,30mg Shire     PS       DAY; 20MG 2       PER DAY   Date:02/11/02ISR Number: 3869110-1Report Type:Expedited (15-DaCompany Report #US0203100 Age: Gender:Male I/FU:I Outcome PT Report Source Product Role Manufacturer	Route	Manufacturer	Role	Product	Report Source	PT		
30MG 2 PER DAY; 20MG 2 PER DAY Date:02/11/02ISR Number: 3869110-1Report Type:Expedited (15-DaCompany Report #US0203100 Age: Gender:Male I/FU:I Outcome PT Report Source Product Role Manufacturer		Shiro	DC			Medication Error		
PER DAY Date:02/11/02ISR Number: 3869110-1Report Type:Expedited (15-DaCompany Report #US0203100 Age: Gender:Male I/FU:I Outcome PT Report Source Product Role Manufacturer		SHILE	25	10,20,30mg SHILE	PIOLESSIONAL			30MG 2 PER
Date:02/11/02ISR Number: 3869110-1Report Type:Expedited (15-DaCompany Report #US0203100 Age: Gender:Male I/FU:I Outcome PT Report Source Product Role Manufacturer								DAY; 20MG 2
Age:     Gender:Male     I/FU:I       Outcome     PT     Report Source     Product     Role     Manufacturer								PER DAY
				rt #US0203100	ed (15-DaCompany Repo			
Daga	Route	Manufacturer	Role	Product	Report Source	PT		
Dose Duration Other Hostility Health Adderall Xr PS Professional			PS	Adderall Xr		Hostility		
Date:02/11/02ISR Number: 3869111-3Report Type:Expedited (15-DaCompany Report #US0202800 Age:5 YR Gender:Male I/FU:I				rt #US0202800	ed (15-DaCompany Repo			
Outcome PT Report Source Product Role Manufacturer Dose Duration	Route	Manufacturer	Role	Product	Report Source	PT		
Other Aggression Health Adderall Xr PS 20 MG DAILY			PS	Adderall Xr	Health	Aggression	I	Other
Depression     Professional     Remeron       Hostility     Other     (Mirtazepine)     C			С					20 MG DATHI

Intentional Self-Injury Suicidal Ideation

Date:02/15/02ISR Number: 3870852-2Report Type:Expedited (15-DaCompany Report #US0128401 Age:13 YR Gender:Male I/FU:I

Outcome Dose Other 10 MG BID	Duration	PT	Report Source	Product	Role Manufacturer	Route
		Agitation	Health	Adderall	PS	
		Blood Alkaline Phosphatase Increased Hypercholesterolaemia	Professional	Risperdal (Risperidone)	с	

Date:02/15/02ISR Number: 3870918-7Report Type:Expedited (15-DaCompany Report #US0203200 Age:21 YR Gender:Female I/FU:I

Outcome Dose	Duration		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 90-180 MG	2		Coma	Consumer	Adderall	PS		
	_		Drug Dependence Medication Error Schizophrenia, Paranoid Type					

Freedom Of Information (FOI) Report

Date:02/15/02ISR Number: 3870920-5Report Type:Expedited (15-DaCompany Report #US0203100 Age:14 YR Gender:Female I/FU:I

Outcome			PT	Report Source	Product	Role Manufacturer	Route
Other	Duratic		Grand Mal Convulsion	Other	Adderall	PS	
20 MG QD	18	MON			Vitamins	С	

Date:02/15/02ISR Number: 3870921-7Report Type:Expedited (15-DaCompany Report #US0204000 Age:8 YR Gender:Male I/FU:I

Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other 10 TO 40 MG	2 MON	Abnormal Behaviour	Other	Adderall Xr	PS		
		Agitation Amblyopia Anxiety Aphasia Confusional State Depersonalisation Disorientation Dry Mouth Feeling Abnormal Lethargy Personality Disorder Somnolence Speech Disorder Tic Vision Blurred		Risperdal (Risperidone)	C		
	2ISR Number Gender:Male	: 3870923-OReport Type:Expedite I/FU:F	ed (15-DaCompany Report	: #US0101401			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalizati 10 MG TO 20	ion -	Abnormal Behaviour	Other	Adderall Xr	PS		
Initial or Pr MG	rolonged	Hallucination					

Date:02/21/02ISR Nu Age:19 YR Gender:	umber: 3872625-3Report Type:Di :Male I/FU:I	irect Company Re	eport #CTU 161920			
Outcome Dose Durati	PT ion	Report Source	Product	Role	Manufacturer	Route
Life-Threatening Hospitalization - 20MG 2 X /DA	Hepatic Trauma Polytraumatism	Health Professional	Adderall/Shire Richwood Corp	PS	Shire Richwood Corp	
Initial or Prolonge	ed Psychotic Disorder Self Injurious Behaviour Spinal Fracture	r				
Date:02/26/02ISR Nu Age:9 YR Gender:	umber: 3875915-3Report Type:Ex :Female I/FU:I	xpedited (15-DaCompany R€	≥port #US-02-033			
Outcome Dose Durati	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 10 MG BID	Anorexia	Health	Adderall	PS		
Initial or Prolonge	ed Haematuria Hypernatraemia Pyrexia Weight Decreased	Professional				

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:03/01/02ISR Number: 3878756-6Report Type:Expedited (15-DaCompany Report #US0205100 Age: Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Other Anxiety Health Adderall Xr PS 10 MG Panic Attack Professional Company Representative Date:03/05/02ISR Number: 3879695-7Report Type:Expedited (15-DaCompany Report #US0205900 Age:9 YR Gender: Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Duration Dose Aggression Other Adderall Xr PSOther 20 MG Clonidine С Injury Personality Disorder Screaming Date:03/06/02ISR Number: 3879596-4Report Type:Direct Company Report #CTU 162893 Gender:Male Aqe: I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Adderall Life-Threatening Aggression PS ORAL 1.5 TABLE X 1 Hospitalization -Blood Pressure Systolic DOSE ORAL Initial or Prolonged Increased Grand Mal Convulsion Required Intervention to Headache Prevent Permanent Mental Status Changes Impairment/Damage Postictal State

Subarachnoid Haemorrhage

Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other 20 MG	Duration	Asthenia	Health	Adderall Xr	PS	
	/02ISR Number Gender:Male	Blood Pressure Increased Difficulty In Walking Dizziness Hallucination Hallucination, Auditory Hallucination, Visual Hypersensitivity Muscle Spasms Tremor	Professional dited (15-DaCompany R	eport #US0207300		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration		-			
Other ONE 10 MG XR	XR	Convulsion	Health	Adderall Xr	PS	
		Partial Seizures	Professional			

Freedom Of Information (FOI) Report

Date:03/18/02ISR Number: 3884753-7Report Type:Expedited (15-DaCompany Report #US0205500 Age:6 YR Gender:Male I/FU:I

Outcome		РТ	Report Source	Product	Role	Manufacturer	Route
Dose Other 10 MG BID	Duration	Convulsion	Consumer	Adderall	PS		
10 110 212			Other				

Date:03/21/02ISR Number: 3887379-4Report Type:Expedited (15-DaCompany Report #A205806 Age:3 YR Gender:Male I/FU:I

Outcome	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Required 25.00 MG	Duration	Abdominal Pain Upper	Consumer	Zoloft Tablets	PS	ORAL
Intervention TOTAL:DAILY:		Abnormal Behaviour				
Prevent Perm RAL	anent	Aggression				
Impairment/Damage ORAL	amage	Anorexia		Adderall	SS	ORAL
		Atypical Attention Deficit Syndrome Cough Crying Dehydration Diarrhoea Emotional Disorder Impulsive Behaviour Insomnia Irritability Mania Mood Altered Viral Infection Vomiting				

Date:03/22/02ISR Number: 3887544-6Report Type:Expedited (15-DaCompany Report #US0206300 Age:9 YR Gender:Female I/FU:I

 $\mathbf{PT}$ 

			Antinuclear Antibody	Health	Adderall	PS		
15 MG	1	YR	Positive Weight Decreased	Professional	Wellbutrin (Bupropion)	С		
Date:03/22/ Age:11 YR	/02ISR Nu Gender:		: 3887545-8Report Type:Exp le I/FU:I	pedited (15-DaCompany R	eport #US0206400			
Outcome Dose	Durati	07	PT	Report Source	Product	Role	Manufacturer	Route
Other 10 MG	l Duraci	YR	Albuminuria	Other	Adderall	PS		

Zoloft (Sertraline) C

Date:03/22/02ISR Number: 3887728-7Report Type:Expedited (15-DaCompany Report #JS0205700

Age:14 YR Gender:Male I/FU:I

Outcome Death PT Arrhythmia Cardiac Arrest Cardiomegaly Drug Level Above

Influenza Like Illness

Asthenia Depression Fatigue

Pyrexia

Protein Urine

			FDA - Adver	se Event Reporting Syste	em (AEF	RS)	
			Freedom	Of Information (FOI) Re	eport		
		Therapeutic Dyspnoea					
	Direction		Report Source	Product	Role	Manufacturer	Route
Dose	Duration		Health Professional Other	Adderall	PS		
Date:03/22/ Age:10 YR	02ISR Number Gender:Male	r: 3887732-9Report Type:Exped: e I/FU:I	ited (15-DaCompany Rep.	ort #US0209400			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Convulsion	Health	Adderall Xr	PS		ļ
20 MG		Depressed Level Of Consciousness Fall Head Injury Staring	Professional				
Date:03/26/ Age:	02ISR Number Gender:Male	r: 3889802-8Report Type:Direct e I/FU:I	t Company Rep	oort #CTU 164225			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 1 PO QD	Duration	Muscle Twitching		Adderall Xr 20 Mg	PS		ORAL
Date:03/28/ Age:19 YR	02ISR Number Gender:Male	r: 3892243-0Report Type:Exped: e I/FU:I	ited (15-DaCompany Rep	ort #US0209300			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitaliza 20MG		Attention	Other	Adderall Xr	PS		
Initial or :	Prolonged	Deficit/Hyperactivity Disorder Condition Aggravated Hostility Pharmaceutical Product		Buspar (Buspirone) Neurontin (Gabapentin) Dilantin (Phenytoin) Inderal La	C C C		

Complaint	t
Physical	Assault

(Propranolol) C Inderal (Propranolol) C Lomotil (Diphenoxylate Hcl With Atropine Sulfate) C Luvox (Fluvoxamine) C Sequel C

Date:04/01/02ISR Number: 3893552-1Report Type:Expedited (15-DaCompany Report #US0209800 Age: Gender:Female I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
1 MON	Duración	Colitis	Other	Adderall Xr	PS	
		Depression Emotional Disorder Irritable Bowel Syndrome				

			$FDA - Adv\epsilon$	erse Event Reporting Syst	tem (AEF	RS)	
			Freedc	om Of Information (FOI) R	Report		
Date:04/01/ Age:12 YR	/02ISR Number Gender:Male	e: 3893553-3Report Type:Expe e I/FU:I	edited (15-DaCompany Re	port #US0204200			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
20 MG AM, 1		Antinuclear Antibody	Other	Adderall	PS		
MG PM	3 YR	Positive Syncope		Clonidine	C		
Date:04/04/ Age:	/02ISR Number Gender:	r: 3895548-2Report Type:Dire I/FU:I	ect Company Re	eport #USP 54804			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duracien	Medication Error		Adderall Adderall Xr	PS SS	Shire Richwood Shire Richwood	
Date:04/05/ Age:9 YR	/02ISR Number Gender:Fema	er: 3896744-0Report Type:Expe male I/FU:I	edited (15-DaCompany Re	port #US0207600			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 2.5 MG TID		Convulsion	Literature	Adderall	PS		
2.5 m			Health Professional				
Date:04/08/ Age:	/02ISR Number Gender:Male	r: 3898247-6Report Type:Dire e I/FU:I	ect Company Re	eport #CTU 165105			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duración	Aggression Condition Aggravated		Adderall (Generic) 10 Mg/Barr Labs	PS	Barr Labs	ORAL
10 MG 1/2 Q	ДА	Drug Ineffective		,			-
1/2 NOON &							
1/2 Q 330PM	М	Hypersensitivity					

PO		Impulsive Behaviour					
		Pharmaceutical Product Complaint					
Date:04/08, Age:	/02ISR Number: Gender:Male	: 3898277-4Report Type:Direct I/FU:I	Company Repor	rt #CTU 165179			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duración	Attention Deficit/Hyperactivity		Adderall (Generic) Barr Labs.	PS	Barr Labs	
5 MG TWICE	Q	Disorder					
AM (SEE IMAGE)		Pharmaceutical Product					
111102 /		Complaint					
Date:04/15, Age:	/02ISR Number: Gender:Male	: 3901361-XReport Type:Expedit I/FU:I	ed (15-DaCompany Repor	rt #US0211600			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 40 MG	5 MON	Grand Mal Convulsion	Health	Adderall Xr	PS		
			Professional				

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:04/17/02ISR Number: 3903012-7Report Type:Expedited (15-DaCompany Report #US0212800 Age:6.5 YR Gender:Male I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Duration Dose Other Anorexia Health Adderall Xr PS 30 TO 60 MG Insomnia Professional Medication Error Speech Disorder Stupor Weight Decreased Date:04/17/02ISR Number: 3903976-1Report Type:Periodic Company Report #US0115700 Gender:Male Age:17 YR I/FU:I Role Manufacturer Outcome ΡТ Report Source Product Route Dose Duration Hospitalization -Psychotic Disorder Health Adderall PS ORAL 10 MG PO Initial or Prolonged Professional Risperdal (Risperidone) С Date:04/17/02ISR Number: 3903977-3Report Type:Periodic Company Report #US0123900 Age:5 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Dysthymic Disorder Other Paxil PS 10 MG DAILY Initial or Prolonged Adderall Nightmare SS SEE NARRATIVE Psychotic Disorder Date:04/18/02ISR Number: 3903274-6Report Type:Expedited (15-DaCompany Report #US0207500 Age:50 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Other Alcoholism Consumer Adderall Xr PS

20 MG

		Attention		Celexa (Citalopram)	С		
		Deficit/Hyperactivity		Neurontin			
		Disorder		(Gabapentin)	С		
		Depression					
		Feeling Jittery					
		Increased Appetite					
		Insomnia					
		Nervousness					
		Psychotic Disorder					
		Suicidal Ideation					
		Weight Decreased					
9							
		: 3906064-3Report Type:E:	xpedited (15-DaCompany Re	eport #US0209400			
	02ISR Number Gender:Male		xpedited (15-DaCompany Re	eport #US0209400			
			xpedited (15-DaCompany Re Report Source	eport #US0209400 Product	Role	Manufacturer	Route
Age:12 YR		I/FU:I			Role	Manufacturer	Route
Age:12 YR Outcome	Gender:Male	I/FU:I			Role PS	Manufacturer	Route
Age:12 YR Outcome Dose Other	Gender:Male	PT	Report Source	Product		Manufacturer	Route
Age:12 YR Outcome Dose Other	Gender:Male	PT Convulsion	Report Source Health	Product		Manufacturer	Route
Age:12 YR Outcome Dose Other 30 MG AM,	Gender:Male	PT Convulsion	Report Source Health	Product		Manufacturer	Route
Age:12 YR Outcome Dose Other 30 MG AM,	Gender:Male	I/FU:I PT Convulsion Disorientation Fall	Report Source Health	Product		Manufacturer	Route
Age:12 YR Outcome Dose Other 30 MG AM,	Gender:Male	I/FU:I PT Convulsion Disorientation	Report Source Health	Product		Manufacturer	Route

Freedom Of Information (FOI) Report

Date:04/23/02ISR Number: 3906065-5Report Type:Expedited (15-DaCompany Report #US-02-093-00 Age:13 YR Gender:Male I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Abdominal Pain Anorexia Dehydration Diarrhoea Dizziness Drug Hypersensitivity Emotional Disorder Nausea Nervousness Pyrexia Vomiting Weight Decreased	Consumer Other	Adderall	PS		
	Gender:Fema	r: 3906385-4Report Type:Expedite ale I/FU:I	ed (15-Dacompany repor	C #HQIYUIII&Ark2002			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat: Initial or Pr Disability ORAL		Mania Schizoaffective Disorder N	Health Professional Company	Effexor Xr (Venlafaxine Hydrochloride)	PS		ORAL
0.011	±•		Representative	Adderall (Amfetamine Aspartate/Amfetamine Sulfate/Dexamfetamin			
25 MG 2X PER	R			e Saccharate/Dexamfeta	SS		ORAL
1 DAY, ORAL							
	2ISR Number Gender:Male	r: 3906951-6Report Type:Direct e I/FU:I	Company Repor	rt #CTU 166629			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Abdominal Pain		Adderall 10 Mg			

		Drug Effect Decreased		Generic	PS	ORAL
10 MG BID PO		Pharmaceutical Product				
		Complaint				
		Psychomotor Hyperactivity				
	2ISR Number: Gender:Male	: 3906962-0Report Type:Direct I/FU:I	Company Report	t #CTU 166632		
		PT	Devent Course	Des - Jacob	Role Manufacturer	Pouto
Outcome Dose	Duration	P.T.	Report Source	Product	Role Manufacturer	Route
Other 20 MG 1 1/2	ther	Abnormal Behaviour		Generic Adderall	PS	ORAL
·		Disturbance In Attention				
AM 1/2 NOON		Educational Problem				
PO		Memory Impairment		Risperdal	С	
		Pyromania		Zoloft	c	
	2ISR Number: Gender:Femal	: 3907629-5Report Type:Expedite le I/FU:I	ed (15-DaCompany Repor	t #US0214800		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 30 MG		Grand Mal Convulsion	Other	Adderall Xr	PS	

Freedom Of Information (FOI) Report

Date:04/25/02ISR Number: 3907898-1Report Type:Expedited (15-DaCompany Report #US0209700 Age:7 YR Gender:Male I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - 5 MG	Abdominal Pain Upper	Other	Adderall	PS	
Initial or Prolonged 5 MG	Blood Pressure Increased		Adderall	SS	
	Cardiac Murmur Circulatory Collapse Condition Aggravated Confusional State Disorientation Face Oedema Heart Rate Increased Movement Disorder Oedema Genital Oedema Peripheral Pallor Paraesthesia Pericardial Effusion Testicular Swelling White Blood Cell Count Increased		Palmocot Claritin 10	C C	
Date:04/29/02ISR Numb Age:6 YR Gender:Fe	er: 3908333-XReport Type:Direct male I/FU:I	Company Rep	ort #CTU 166752		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
	Drug Effect Decreased Pharmaceutical Product		Adderall (Generic) 10	PS	
10MG 1 TABLET	Complaint				
QD	Rash				
Date:04/30/02ISR Numb Age: Gender:Ma	er: 3909424-XReport Type:Direct le I/FU:I	Company Rep	ort #CTU 166890		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route

		Aggression	Health	Adderall-Generic -5g			
ORAL BID		Drug Effect Decreased	Professional	(3 In Am, 2@ Noon)	PS		ORAL
URAL DID		Negativism					
15G, 10G		109401.22					
		Pharmaceutical Product Complaint					
	02ISR Number Gender:Male	: 3910715-7Report Type:Expe I/FU:I	edited (15-DaCompany Re	eport #US0209500			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other	1 170	Aggression	Other	Adderall	PS		
90 MG	1 YR	**]					
		Hostility Insomnia					
		Medication Error					
		Psychotic Disorder					
	02ISR Number Gender:	: 3911533-6Report Type:Dire I/FU:I	ect Company Re	eport #CTU 167175			
Outcome		PT	Report Source	Product	Pole	Manufacturer	Route
Dose	Duration	PI	KEDOLC BOULCE	PIOUUCC	VOIC	Mallulactuler	Route
Other	Durucron	Anorexia		Adderall	PS		
				Prozac	C		
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			FDA – Adve	erse Event Reporting Sys	stem (AERS)	
			Freedo	om Of Information (FOI)	Report	
Date:05/02, Age:	/02ISR Number Gender:Male	r: 3911438-OReport Type:Direc I/FU:I	t Company Re	eport #CTU 167200		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other I PO Q AM	Duración	Hallucination, Auditory		Adderal Xr 20mg	PS	ORAL
1 10 Q AN		Pharmaceutical Product Complaint				
Date:05/02/ Age:5 YR	/02ISR Number Gender:Male	r: 3911585-3Report Type:Exped I/FU:I	lited (15-DaCompany Re	eport #US0209800		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 10MG TO 15		Drug Ineffective	Health	Adderall	PS	
1046 10 15	no	Head Banging Injury	Professional	Clonidine	С	
Date:05/02/ Age:5 YR	/02ISR Number Gender:Male	r: 3911586-5Report Type:Exped E I/FU:I	lited (15-DaCompany Re	eport #US0214600		
Outcome	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Other 10 MG	Duración	Drug Ineffective	Health	Adderall Xr	PS	
IO MG		Head Banging Injury	Professional	Clonidine	C	
Date:05/02, Age:15 YR	/02ISR Number Gender:Male	: 3911587-7Report Type:Exped I/FU:I	lited (15-DaCompany Re	eport #US0216100		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other 10 MG TO 20	Duration	Grand Mal Convulsion	Other	Adderall Xr	PS	
TO MRG IO 20	UMG			Minocycline	C	

	2ISR Number: Gender:Male	: 3913521-2Report Type:Expedit I/FU:I	ed (15-:	DaCompany Repor	t #US0211000			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other	2 4	Abdominal Pain Upper Bipolar Disorder Cardiac Murmur	Other		Adderall Zyprexa (Olanzapine) Trileptal	PS C		
		Dizziness Headache Overdose			(Oxcarbazepine)	С		
	2ISR Number: Gender:Male	: 3913866-6Report Type:Direct I/FU:I		Company Repor	t #CTU 167596			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other 1 PO Q AM	Duración	Hallucination, Auditory			Adderall Xr 20mg	PS		ORAL
1 10 9 101		Pharmaceutical Product Complaint						
	2ISR Number: Gender:Male	: 3914750-4Report Type:Direct I/FU:I		Company Repor	t #CTU 167799			
Outcome		PT Attention Deficit/Hyperactivity						
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Freedom Of Information (FOI) Report

				-F		
Duration	Disorder Condition Aggravated Disturbance In Attention Drug Ineffective	Report Source	Product	Role	Manufacturer	Route
	Impulsive Behaviour Pharmaceutical Product		Adderall (Generic) Barr Labs	PS	Barr Labs	
Q						
n 2 mon						
		lited (15-DaCompany Re	port #US0217100			
	PT	Report Source	Product	Role	Manufacturer	Route
Duration	Haematuria Hypertension		Adderall Xr	PS		
	PT	Report Source	Product		Manufacturer	Route
	Hallucination	Health	Adderall Xr	PS		
	Medication Error Paranoia	Professional Company Representative	Zoloft	С		
		lited (15-DaCompany Re	port #US0211300			
Duration	PT	Report Source	Product	Role	Manufacturer	Route
Duration	Abdominal Pain Upper	Other	Adderall	PS		
	Abnormal Behaviour Convulsion Headache Insomnia Thinking Abnormal					
	Q N 2 MON D2ISR Number Gender:Fema Duration D2ISR Number Gender:Male Duration	Condition Aggravated Disturbance In Attention Drug Ineffective Duration Impulsive Behaviour Pharmaceutical Product Complaint N 2 MON D2ISR Number: 3915545-8Report Type:Expect Gender:Female I/FU:I Duration D2ISR Number: 3916234-6Report Type:Expect Gender:Male I/FU:I Duration PT Duration PT Duration D2ISR Number: 3916235-8Report Type:Expect Gender:Male I/FU:I D2ISR Number: 3916235-8Report Type:Expect Gender:Male I/FU:I D2ISR Number: 3916235-8Report Type:Expect Gender:Male I/FU:I Duration D2ISR Number: 3916235-8Report Type:Expect Gender:Male I/FU:I Duration D2ISR Number: 3916235-8Report Type:Expect Gender:Male I/FU:I Duration Abdominal Pain Upper Abnormal Behaviour Convulsion Headache Insomnia	Condition Aggravated Disturbance In Attention Drug Ineffective Report Source Impulsive Behaviour Pharmaceutical Product Complaint N 2 MON DISER Number: 3915545-8Report Type:Expedited (15-DaCompany Re Gender:Female I/FU:I PT Report Source Duration Haematuria Hypertension DISER Number: 3916234-6Report Type:Expedited (15-DaCompany Re Gender:Male I/FU:I PT Report Source Duration Hallucination Health Medication Error Professional Paranoia Company Representative DISER Number: 3916235-8Report Type:Expedited (15-DaCompany Re Gender:Male I/FU:I PT Report Source Duration Paranoia Company Representative DISER Number: 3916235-8Report Type:Expedited (15-DaCompany Re Gender:Male I/FU:I PT Report Source Duration Duration Paranoia Company Representative Duration PT Report Source Duration Abdominal Pain Upper Other Abnormal Behaviour Convulsion Headache Insomnia	Duration Condition Aggravated Disturbance In Attention Drug Ineffective Report Source Product   Impulsive Behaviour Pharmaceutical Product Adderall (Generic) Barr Labs   Q Complaint   Q Complaint   21SR Number: 3915545-8Report Type:Expedited (15-DaCompany Report #US0217100 Gender:Femile I/FU:I   Puration PT   Puration Report Source   Puration PT   Puration S916234-6Report Type:Expedited (15-DaCompany Report #US0217400 I/FU:I   Puration PT   Puration Report Source   Puration PT   Puration PT   Puration Product   Puration S916235-8Report Type:Expedited (15-DaCompany Report #US0217400 I/FU:I   Puration PT   Puration PT   Puration PT   Puration PT   Puration Professional Company Representative   Puration S916235-8Report Type:Expedited (15-DaCompany Report #US0211300 Company Representative   PUTATION PT   PUTATION PT <t< td=""><td>Duration     Condition Agravated Disturbance In Attention Drug Ineffective     Report Source     Product     Role       Impulsive Behaviour Pharmaceutical Product     Adderall (Generic) Barr Labs     PS       Complaint     Complaint     PS       Complaint     Complaint     PS       D2ISR Number:     3915545-8Report Type:Expedited (15-DaCompany Report #US0217100 Gender:Female I/FU'I     Report Source     Product     Role       Duration     PT     Report Source     Product     Role       Duration     Iffuritant     Adderall Xr     PS       D2ISR Number:     3915234-6Report Type:Expedited (15-DaCompany Report #US0217400 Gender:Male     PT     Report Source     Product     Role       Duration     PT     Report Source     Product     Role       Duration     Hallucination     Health     Adderall Xr     PS       Medication Error     Professional Company Representative     Coloft     C       Duration     F     Professional Company Representative     Coloft     C       Duration     PT     Report Source     Product     Role       Duration     F     Professional Company Representative     Profuct     Role       Duration     PT     Report Source     Product     Role       Duration     Abdominal Pain Upper&lt;</td><td></td></t<>	Duration     Condition Agravated Disturbance In Attention Drug Ineffective     Report Source     Product     Role       Impulsive Behaviour Pharmaceutical Product     Adderall (Generic) Barr Labs     PS       Complaint     Complaint     PS       Complaint     Complaint     PS       D2ISR Number:     3915545-8Report Type:Expedited (15-DaCompany Report #US0217100 Gender:Female I/FU'I     Report Source     Product     Role       Duration     PT     Report Source     Product     Role       Duration     Iffuritant     Adderall Xr     PS       D2ISR Number:     3915234-6Report Type:Expedited (15-DaCompany Report #US0217400 Gender:Male     PT     Report Source     Product     Role       Duration     PT     Report Source     Product     Role       Duration     Hallucination     Health     Adderall Xr     PS       Medication Error     Professional Company Representative     Coloft     C       Duration     F     Professional Company Representative     Coloft     C       Duration     PT     Report Source     Product     Role       Duration     F     Professional Company Representative     Profuct     Role       Duration     PT     Report Source     Product     Role       Duration     Abdominal Pain Upper<	

Date:05/13/02ISR Number Age:16 YR Gender:Male	: 3917440-7Report Type:Periodi I/FU:I	c Company Report	t #US0212300			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 20 MG	Drug Dependence	Health	Adderall Xr	PS		
Initial or Prolonged	Overdose Psychotic Disorder	Professional Company Representative	Creatine And Other Otcs	С		
Date:05/13/02ISR Number Age:33 YR Gender:Fema	: 3917441-9Report Type:Periodi le I/FU:I	c Company Report	t #US0209900			
		c Company Report Report Source	t #US0209900 Product	Role	Manufacturer	Route
Age:33 YR Gender:Fema Outcome	le I/FU:I			Role PS	Manufacturer	Route
Age:33 YR Gender:Fema Outcome Dose Duration Hospitalization -	le I/FU:I PT	Report Source	Product		Manufacturer	Route

				e Event Reporting Syste		RS)	
			Freedom C	Of Information (FOI) Re	port		
	02ISR Number: Gender:Male	: 3917442-0Report Type:Periodic I/FU:I	c Company Repor	rt #US0205400			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat 30 MG		Agitation	Health	Adderall Xr	PS		I
Initial or H	-	Psychotic Disorder	Professional				
	02ISR Number: Gender:Femal	: 3918748-1Report Type:Expedite le I/FU:I	ed (15-DaCompany керог	:t #US0217600			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 10 MG		Cough	Health	Adderall Xr	PS		I
IU MG		Hypersensitivity Oedema Pallor Pruritus	Professional Company Representative				
	02ISR Number: Gender:Male	: 3919328-4Report Type:Direct I/FU:I	Company Repoi	rt #CTU 168467			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose		Attention Deficit/Hyperactivity		Adderall (Generic) Barr Labs	PS	Barr Labs	ORAL
3MG 1T QAM 1	1T	Disorder					-
Q NOON PO		Condition Aggravated Disturbance In Attention Irritability Pharmaceutical Product Complaint					
Date:05/21/0 Age:7 YR	02ISR Number: Gender:Male	: 3919332-6Report Type:Direct I/FU:I	Company Repoi	rt #CTU 168468			

Outcome	Dunation	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 15MG PO QID	Duration	Drug Effect Decreased		Adderall (Generic)	PS		ORAL
		Pharmaceutical Product Complaint					
	)2ISR Number Gender:	: 3920102-3Report Type:Direct I/FU:I	Company Repor	t #CTU 168659			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Jose Dura		Drug Effect Decreased Pharmaceutical Product		Adderall 10mg Generic And Brand			
1 1/2 PO BID	) 3 MON	Complaint		Name	PS		ORAL
Date:05/22/0 Age:14 YR		: 3920916-XReport Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #US0212700			
Outcome		PT					
Hospitalizat Initial or F		Drug Screen Positive Drug Toxicity Headache Hyperhidrosis Hypertension Mental Status Changes Overdose					
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Freedom Of Information (FOI) Report

Dose 4 TABLETS	Duration	Status Epilepticus Vomiting	Report Source Literature	Product Adderall	Role PS	Manufacturer	Route
	02ISR Number Gender:Male	r: 3925090-1Report Type:Expec e I/FU:I	dited (15-DaCompany Re	eport #US0212200			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Other SEE NARRATIV		Balance Disorder Cerebrovascular Accident Convulsion Coordination Abnormal Drug Screen Positive Electroencephalogram Abnormal Headache Heart Rate Increased Insomnia Lacunar Infarction Nuclear Magnetic Resonance Imaging Abnormal Syncope Thyroid Function Test Abnormal Tremor	Other	Adderall	PS		
	02ISR Number Gender:Male	r: 3926562-6Report Type:Expec e I/FU:I	dited (15-DaCompany Re	eport #US0219800			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 30 MG	Duración	Abnormal Behaviour	Other	Adderall Xr	PS		
5 OR 10 MG		Aggression Attention Deficit/Hyperactivity		Generic Amphet	SS		

## Disorder

Date:05/29/02ISR Number: 3926567-5Report Type:Expedited (15-DaCompany Report #US0219100 Age:16 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Hospitalizat SEE NARRATIV		Aggression	Company	Adderall Xr	PS	
Initial or P SEE NARRATIV	-	Delusion	Representative	Adderall	SS	
		Drug Level Above Therapeutic Intentional Misuse Psychotic Disorder	Other			
Date:05/29/0	2ISR Number	: 3926636-XReport Type:Expe	dited (15-DaCompany Re	port #US0219000		

Age:8 YR Gender:Male I/FU:I

Outcome Other PT Emotional Disorder Epistaxis Mood Altered Mood Swings

Freedom Of Information (FOI) Report

Dose 1/2 OF 20-M CAP	Duration IG	Posture Abnormal Tremor	Report Source Consumer Other	Product Adderall Xr	Role PS	Manufacturer	Route
Date:06/04/0 Age:1 YR	02ISR Number Gender:Male	: 3929105-6Report Type:Expedite I/FU:I	.ed (15-DaCompany Repor	t #US0219600			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 10 MG	Duration	Agitation	Other	Adderall Xr	PS		ļ
		Anorexia Crying Emotional Disorder Eye Haemorrhage Psychomotor Hyperactivity		"Seizure Medication"	С		
Date:06/06/0 Age:10 YR	02ISR Number Gender:Male	: 3928915-9Report Type:Direct I/FU:I	Company Report	t #CTU 169617			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 20 PO BID	Duration	Drug Ineffective Pharmaceutical Product Complaint		Adderall-Generic Through Barr Manufacturing	PS	Barr	ORAL
Date:06/06/0 Age:38 YR	02ISR Number Gender:Male	: 3930075-5Report Type:Expedite I/FU:I	ed (15-DaCompany Repor	t #US0213000			
Outcome	Description	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Injury	Other	Adderall	PS		

	С	Company Report	. #2001-08-2365			
1/F0:1						I
PT	Report S	Source	Product	Role	Manufacturer	Route
Agitation	Health		Meridia			1
Convulsion	Professi	lonal	(Sibutramine)	PS		ORAL
Depression	Other		Adderall			l
Headache			(Dextroamphetamine/A			
Hyperaesthesia			mphetamine)	SS		ORAL
						I
Hypertension			Claritin			
			(Loratadine) Tablets	SS		ORAL
	I/FU:I PT Agitation Convulsion Depression Headache Hyperaesthesia	I/FU:I PT Report S Agitation Health Convulsion Professi Depression Other Headache Hyperaesthesia	I/FU:I Report Source Agitation Health Convulsion Professional Depression Other Headache Hyperaesthesia	I/FU:I Report Source Product Agitation Report Source Meridia Convulsion Professional (Sibutramine) Depression Other Adderall Headache Hyperaesthesia Other Claritin	I/FU:IReport SourceProductRoleAgitation ConvulsionHealth ProfessionalMeridia (Sibutramine)PSDepression Headache HyperaesthesiaOther LAdderall (Dextroamphetamine/A mphetamine)SS	I/FU:IReport SourceProductRole ManufacturerAgitation ConvulsionHealth ProfessionalMeridia (Sibutramine)PSDepression Headache HyperaesthesiaOther Low Low Low Metamine)Adderall (Dextroamphetamine/A mphetamine)SSHypertensionClaritin

## Date:06/11/02ISR Number: 3933486-7Report Type:Expedited (15-DaCompany Report #US0213600 Age: Gender:Male I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other			Health Professional Company Representative	Adderall	PS	

		FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report					
		FIEEdoli	or information (FOI)	Report			
Date:06/14/02ISR Numbe Age:9 YR Gender:Mal	r: 3933330-8Report Type:Direct e I/FU:I	Company Rep	ort #CTU 170164				
Outcome Dose Duration	PT Drug Ineffective	Report Source	Product Adderall 5mg	Role Manufacturer PS	Route		
5MG 2TT	Pharmaceutical Product Complaint						
Date:06/14/02ISR Numbe Age:9 YR Gender:Mal	r: 3934424-3Report Type:Direct e I/FU:I	Company Rep	ort #CTU 170212				
Outcome	PT	Report Source	Product	Role Manufacturer	Route		
Dose Duration	Drug Effect Decreased Pharmaceutical Product Complaint		Adderall 5mg	PS			
Date:06/17/02ISR Numbe Age:42 YR Gender:Fem	r: 3934799-5Report Type:Direct ale I/FU:I	Company Rep	ort #CTU 170281				
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route		
Hospitalization - Initial or Prolonged Disability Required Intervention to Prevent Permanent Impairment/Damage	Anger Bipolar Disorder Crying Fear Feeling Abnormal Hallucination, Auditory Loss Of Employment Memory Impairment Paranoia Personality Change Thinking Abnormal		Ritalin Adderall	PS SS			

Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other 20 MG	Duration	Dyspnoea	Health	Adderall Xr	PS	
	21SR Number	<pre>Face Oedema Heart Rate Increased Hyperhidrosis Nervousness Oedema Peripheral Paraesthesia Tachycardia Tooth Disorder Tremor</pre>	Professional Company Representative ted (15-DaCompany Repor	Axid (Nizatidine) ct #US0215100	С	
Age:	Gender:Male	I/FU:I				
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalizat Initial or P Disability	ion -	Injury Psychotic Disorder	Other	Adderall	PS	

	FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report							
	02ISR Number Gender:Male	: 3946777-0Report Type:Direct I/FU:I	Company Repo	rt #CTU 172066				
Outcome Dose Other	Duration	PT Agitation Drug Ineffective Malaise Pharmaceutical Product Complaint	Report Source	Product Adderall 10 Mg- Generic 1 Dly	Role PS	Manufacturer	Route	
	02ISR Number Gender:Fema	: 3947925-9Report Type:Expedi le I/FU:I	ted (15-DaCompany Repo	rt #US0214500				
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route	
Other 1 YR	Daración	Convulsion	Health	Adderall	PS			
			Professional	Hydrocodone Ibuprofen Imitrex (Sumatriptan Succinate)	C C C			
Date:07/11/( Age:	02ISR Number Gender:Male	: 3948683-4Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	rt #US0214900				
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route	
Other 10 MG	242402011	Hyperglycaemia	Consumer	Adderall	PS			
		Hypertension Tachycardia		Glucotrol Xl (Glipizide) Glucophage (Metformin Hydrochloride)	C			

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Anorexia	Other	Adderall Xr	PS		
		Asthenia					
		Gait Disturbance					
		Movement Disorder					
		: 3954214-5Report Type:Expedi	ted (15-DaCompany Repo	rt #US0223201			
Age:11 YR	Gender:Male	E I/FU:F					
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Disability 30 MG		Abnormal Behaviour	Other	Adderall Xr	PS		
Other		Anorexia					
		Asthenia					
		Cerebral Palsy					
		Condition Aggravated					
		Difficulty In Walking					
		Gait Disturbance					
		Movement Disorder					
		Myasthenic Syndrome					
4							,

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:07/29/02ISR Number: 3956088-5Report Type:Expedited (15-DaCompany Report #US0215700 Age:12 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Dysphemia Other Adderall PS 2 YR 10 MG TID Petit Mal Epilepsy Date:07/29/02ISR Number: 3956090-3Report Type:Expedited (15-DaCompany Report #US0215500 Age:42 YR Gender:Female I/FU:I Outcome ΡТ Report Source Product Role Manufacturer Route Dose Duration Blood Test Abnormal Consumer Adderall Other PS 20 MG Breast Cancer Stage Iii Risperdal (Risperidone) Metastases To Central С Diazide С Nervous System Sinus Disorder Date:08/07/02ISR Number: 3960115-9Report Type:Expedited (15-DaCompany Report #US0225000 Gender: Female I/FU:I Age: Role Manufacturer PTReport Source Product Outcome Route Dose Duration Other Feeling Cold Consumer Adderall Xr PS SEE NARRATIVE Hypothyroidism Ritalin SS Memory Impairment Birth Control Pills С Wellbutrin (Buproprion Hydrochloride) ("Not On Long") С Prozac (Fluoxetine Hydrochloride) (Not On Long) С

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 20 MG/SEE	Duration	Petit Mal Epilepsy	Other	Adderall	PS		
NARRATIVE				Asthma Medication	С		
Date:08/14/ Age:	02ISR Number Gender:Male	: 3962233-8Report Type:Direct I/FU:I	Company Repor	t #CTU 174117			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Required	Duration	Anorexia		Adderall Xr 20mg			
Interventio	n + 0	Depression		Shire Us	PS	Shire Us	ORAL
20MG CAPSUL		Depression		SHILE US	ΕIJ	SHILE 05	01/AU
Prevent Per ORAL Impairment/	manent	Insomnia					
Date:08/20/ Age:6 YR	02ISR Number Gender:Male	: 3965295-7Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #US0226000			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other 20 MG	Duración	Anger	Other	Adderall Xr	PS		
		Hostility		Paxil (Paroxetine Hydrochloride)	С		
1							

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:08/20/02ISR Number: 3965309-4Report Type:Expedited (15-DaCompany Report #US0225700 Aqe:16 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Other Hostility Other Adderall Xr PS 20 MG Adderall Injury SS 20 MG A.M. Personality Disorder Physical Assault Screaming Date:08/26/02ISR Number: 3967029-9Report Type:Direct Company Report #CTU 175035 Gender:Male Aqe:12 YR I/FU:I Report Source Role Manufacturer Outcome PTProduct Route Dose Duration Other Antibody Test Positive Adderall 20mg PS ORAL 20MG PO QD Date:08/26/02ISR Number: 3967030-5Report Type:Direct Company Report #CTU 175036 Age:14 YR Gender:Female I/FU:I Role Manufacturer PTReport Source Outcome Product Route Dose Duration Other Coagulopathy Adderall 20mg PS ORAL 20MG PO QD Date:08/26/02ISR Number: 3967031-7Report Type:Direct Company Report #CTU 175037 Age:12 YR Gender:Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Coagulopathy Adderall PS ORAL 15MG PO QD

Date:08/26/02ISR Number: 3967032-9Report Type:Direct Age:14 YR Gender:Female I/FU:I

	I Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 20MG PO QD	Duración	Antinuclear Antibody Positive Coagulopathy		Adderall	PS		ORAL
	)2ISR Number Gender:Male	: 3967033-0Report Type:Direct I/FU:I	Company Repor	t #CTU 175039			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 45MG PO DAII		Coagulopathy		Adderall	PS		ORAL
Date:08/27/( Age:9.5 YR		: 3969229-0Report Type:Expedit	ed (15-DaCompany Repor	t #US0216500			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10 MG 1 TIME		Convulsion	Health	Adderall	PS		
1 DOSE	_		Professional				
Date:08/28/( Age:26 YR		: 3968029-5Report Type:Direct I/FU:I	Company Repor	t #CTU 175228			
Outcome Other		PT Anger Depression					
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Freedom Of Information (FOI) Report

Dose 1 DAILY	Duration	Dyspnoea Emotional Disorder Malaise Mania Palpitations	Report Source	Product Adderal 30 Mg	Role PS	Manufacturer	Route
Date:08/28, Age:12 YR	/02ISR Number Gender:Male	r: 3968786-8Report Type:Expedit e I/FU:I	ed (15-DaCompany Repor	t #US0227800			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
10 MG	Duration	Hypoaesthesia	Other	Adderall Xr	PS		
	/02ISR Number Gender:	r: 3969787-6Report Type:Direct I/FU:I	Company Repor	t #CTU 175417			
Outcome	Dunchion	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 5 MG TWICH	Duration E A	Aggression		Adderall	PS		
DAY							
Date:08/30, Age:8 YR	/02ISR Number Gender:Male	r: 3969819-5Report Type:Direct e I/FU:I	Company Repor	t #CTU 175429			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Drug Ineffective Pharmaceutical Product Complaint		Generic Adderall	PS		

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Headache	Other	Adderall Xr	PS		
UNKNOWN							
		Nausea					
		Nervousness					
		Syncope					
		Tremor					
Data·09/05/(	NUMBER	: 3971971-2Report Type:Exp	odited (15-DaCompany Re				
	Gender:Male		edited (15-bacompany in	20010 #030220300			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
2020	2 41 4 6 1 6 1	Headache	Other	Adderall Xr	PS		
UNKNOWN							
		Nausea					
		Nervousness					
		Syncope					
		Tremor					
	21SR Number Gender:Male	: 3972359-0Report Type:Exp e I/FU:I	edited (15-DaCompany Re	eport #US0229000			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death 10 MG; ONE		Circulatory Collapse	Health	Adderal Xr	PS		
DOGE		Sudden Death	Professional				
DOSE			Company				
			Representative				
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FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:09/05/02ISR Number: 3972679-XReport Type:Expedited (15-DaCompany Report #US0228300 Age:14 YR Gender:Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Headache Consumer Adderall Xr PS Other Nausea Nervousness Syncope Tremor Date:09/11/02ISR Number: 3974571-3Report Type:Expedited (15-DaCompany Report #US0217400 Age:15 YR Gender:Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Duration Dose Adderall Other Intentional Self-Injury Other PSLaceration Marijuana SS Medication Error Personality Change Date:09/11/02ISR Number: 3974600-7Report Type:Expedited (15-DaCompany Report #US0217200 Gender:Male I/FU:I Age: Product Role Manufacturer PTReport Source Outcome Route Dose Duration Oculogyration Other Health Adderall PS Professional Date:09/12/02ISR Number: 3975727-6Report Type:Expedited (15-DaCompany Report #US0229400 Age: 7.5 YR Gender: Male I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Other Partial Seizures Other Adderall Xr PS 10 MG

	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Death 20 MG		Circulatory Collapse	Health	Adderall	PS		
		Drug Toxicity Sudden Death	Professional				
Date:09/19/( Age:	02ISR Number: Gender:	: 3978552-5Report Type:Direct I/FU:I	Company Report	t #CTU 176844			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Drug Effect Decreased		Adderall 30mg / Bid	PS		I
30MG 1 BID		Pharmaceutical Product Complaint					
Date:09/23/( Age:8 YR	02ISR Number: Gender:Male	: 3980052-3Report Type:Direct I/FU:I	Company Report	t #177044			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10 MG QAM AM		Erythema		Adderall Xr	PS	Eon Labs	
		Flushing					I
Q NOON		Skin Warm Tardive Dyskinesia					
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			FDA – Adve	erse Event Reporting Sy	ystem (AERS)	
			Freedo	om Of Information (FOI)	) Report	
	02ISR Number Gender:Fema	r: 3981279-7Report Type:Dire ale I/FU:I	ct Company Re	eport #CTU 177036		
Outcome Dose Other	Duration	PT Drug Ineffective Pharmaceutical Product Complaint	Report Source	Product Adderall Ritalin Gen Dexadrine	Role Manufacturer PS SS SS	Route
	02ISR Number Gender:Male	: 3982225-2Report Type:Expe	dited (15-DaCompany Re			
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Death 20 MG	Duration	Arrhythmia	Health	Generic Dex/Am	PS	
		Cardio-Respiratory Arrest Drug Toxicity Pneumonia Aspiration Sudden Death	Professional			
Date:09/25/ Age:28 YR	02ISR Number Gender:Male	r: 3982857-1Report Type:Expe = I/FU:I	dited (15-DaCompany Re	eport #US0218300		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Other 20 MG TID	Duration	Chest Pain Dizziness	Consumer	Adderall	PS	
		Electrocardiogram Abnormal Tachycardia				
Date:09/27/ Age:	02ISR Number Gender:Fema	r: 3982437-8Report Type:Dire ale I/FU:I	ct Company Re	eport #CTU 177411		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
40 MG		Drug Tolerance Decreased		Adderall	PS	
		Pharmaceutical Product				

		Complaint Vomiting							
	R Number: der:Male	3983341-1Report Type:Direct I/FU:I		Company Report	: #CTU 1775	559			
Outcome		PT	Report	Source	Product		Role	Manufacturer	Route
Dose Du Disability Required 30MG 3X		Aggression Anxiety			Adderall Shire	30 Mg	PS	Shire	ORAL
Intervention to ORAL	)	Depression							
Prevent Permane Impairment/Dama 120MG 1X		Insomnia Psychotic Disorder			Adderall Shire	30mg	SS	Shire	ORAL
ORAL									
	R Number: der:Femal	3983790-1Report Type:Direct e I/FU:I		Company Report	: #CTU 1776	656			
Outcome	ration	PT	Report	Source	Product		Role	Manufacturer	Route
Dose Du 40 MG		Drug Tolerance Decreased			Adderall		PS		
		Pharmaceutical Product Complaint Vomiting							

			FDA - Adve	erse Event Reporting Sys	stem (AERS	S)	
			Freedo	om Of Information (FOI)	Report		
	ISR Number ender:Male	r: 3987812-3Report Type:Exped: e I/FU:I	ited (15-DaCompany Re	port #US0231100			
Outcome Dose I	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Dizziness	Other	Adderall Xr	PS		
SEE NARRATIVE		Palpitations Tachycardia					
	ISR Number ender:Male	: 3987817-2Report Type:Exped: I/FU:I	ited (15-DaCompany Re	port #US0230600			
Outcome Dose I	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other SEE NARRATIVE		Anger	Health	Adderall Xr	PS		
		Emotional Disorder Hostility	Professional	Allegra (Fexofenadine Hydrochloride) Bactrim Fluoxetine	С С С		
	ISR Number ender:Male	: 3985830-2Report Type:Direct I/FU:I	t Company Re	eport #CTU 178022			
Outcome Dose I	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization 1 TABLET PO		Abnormal Behaviour		Adderall 20mg	PS		ORAL
Initial or Pro ORAL	olonged	Aggression					
		Arrhythmia		Zoloft 50mg	SS		ORAL
1 TABLE PO		Crying					
ORAL		Educational Problem Memory Impairment Tremor					

	02ISR Number: Gender:Male	: 3991396-3Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	rt #US0219100			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat 3 OR 4/2000	tion -	Aggression	Consumer	Adderall	PS		
Initial or H	Prolonged	Hostility Screaming	Other				
Date:10/10/( Age:	)2ISR Number: Gender:Male	: 3991074-0Report Type:Direct I/FU:I	Company Repo	rt #CTU 178481			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
DOSE	Duración	Abnormal Behaviour Educational Problem		Adderall 30mg Generic	PS		
30MG BID		Pharmaceutical Product Complaint			15		
	)2ISR Number: Gender:Male	: 3991409-9Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	rt #US0232100			
Outcome		PT Asthenia Delusion Fatigue Increased Appetite Myalgia					
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Freedom Of Information (FOI) Report

Dose 30 MG DAILY	Duration 3 MON	Neoplasm Nuclear Magnetic Resonance Imaging Abnormal	Report Source Consumer	Product Adderall Xr	Role PS	Manufacturer	Route
	)2ISR Number Gender:	: 3991667-0Report Type:Direct I/FU:I	Company Repor	t #CTU 178543			
Outcome	D	PT	Report Source	Product	Role	Manufacturer	Route
Dose 1t po Q Am	Duration	Headache Pharmaceutical Product		Adderall 30mg Amphet Asp/Ampht-/D	PS		ORAL
II PO Q AM		Complaint			SS		
	)2ISR Number Gender:Fema Duration	: 3997215-3Report Type:Expedit le I/FU:I PT Convulsion Vomiting	ed (15-DaCompany Repor Report Source Health Professional Company Representative	rt #US0233300 Product Adderall Xr	Role PS	Manufacturer	Route
	)2ISR Number Gender:Fema	: 4000616-0Report Type:Direct le I/FU:I	Company Repor	t #CTU 179747			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose 10mg Q am an 5mg Q noon		Abnormal Behaviour Contusion		Adderall(Generic)	PS		
[STARTED PTA	<i>Y</i> ]	Hair Plucking Initial Insomnia		Serzone	С		
1				20120110	0		

		Irritability Nightmare		Zyprexa	C	
Date:10/30/ Age:19 YR	02ISR Number Gender:Male	: 4002403-6Report Type:Direct	Company Repoi	rt #CTU 180014		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 1 DOSE	Duracion	Chest Discomfort		Adderall	PS	
1 2002		Heart Rate Increased Tremor		Synthroid	C	
Date:11/01/ Age:16 YR	02ISR Number Gender:Male	r: 4005306-6Report Type:Expedit e I/FU:I	ted (15-DaCompany Repoi	rt #US0220400		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other SEE NARRATI		Hypoaesthesia	Health	Adderall	PS	
		Insomnia Intentional Misuse Tachycardia	Professional			

			FDA - Advers	e Event Reporting Syste	m (AER	2S)	
			Freedom	Of Information (FOI) Re	port		
Date:11/05/0 Age:8 YR	02ISR Number: Gender:Femal	4003940-OReport Type:Direct .e I/FU:I	Company Repo	rt #CTU 180336			
Outcome Dose Other 10-20-30 ON DAILY ORAL	Duration CE	PT Abnormal Behaviour Anxiety Constipation Hair Plucking Sleep Disorder Weight Decreased	Report Source	Product Adderall Xr 10-20 And 30 Mg Shire	Role PS	Manufacturer Shire	Route ORAL
	Gender:Male Duration	4011295-OReport Type:Direct I/FU:I PT Weight Increased	Company Repo Report Source	rt #CTU 181054 Product Zyprexa 5 Mg	Role PS	Manufacturer	Route
QAM/PM,.5MG QHS, 5MG QAM/PM 2.5M0 QHS	5			Adderall Xr 70mg Qam	SS		
70MG QAM 20MG QD 1MG TID				Celexa 20mg Qd Tenex 1mg Tid	SS C		
Date:11/15/0 Age:9 YR	02ISR Number: Gender:Male	4014268-7Report Type:Expedit I/FU:I	ed (15-DaCompany Repo	rt #US0236000			
Outcome Dose Hospitaliza 10 MG A.M.	Duration	PT Drug Toxicity	Report Source Health	Product Adderall Xr	Role PS	Manufacturer	Route

Initial or Other	Prolonged	Neuroleptic Malignant Syndrome Overdose	Professional Company Representative	Depakote (Divalproex Sodium) Risperdal (Risperidone)	C C		
Date:11/19/ Age:	02ISR Number Gender:Fema	: 4012811-5Report Type:Direct le I/FU:I	Company Repo	rt #CTU 181273			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duración	Decreased Appetite Irritability Mood Altered Sleep Disorder		Adderall	PS		
Date:11/21/ Age:5 YR	02ISR Number Gender:Male	: 4016914-0Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	rt #US0219700			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duracion	Bruxism	Other	Adderall	PS		
20 MG ONE		Electroencephalogram					
TIME;		Liedtroencephalogram					
		Abnormal Hallucination Overdose					

			FDA - Adverse	Event Reporting Syste	m (AER	LS)	
			Freedom O	f Information (FOI) Re	port		
Date:11/22/ Age:	02ISR Number Gender:Male	: 4013679-3Report Type:Direct I/FU:I	Company Repor	t #CTU 181529			
Outcome Dose BID- TID PR	Duration N	PT Abdominal Discomfort	Report Source	Product Adderall 20 Generic	Role PS	Manufacturer	Route
	02ISR Number Gender:Male	: 4018066-XReport Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #US0237900			
Outcome Dose Other 10 MG (SEE NARRATIVE F THERAPY DATES)	Duration OR	PT Condition Aggravated Eye Infection Macular Degeneration Visual Acuity Reduced	Report Source Other	Product Adderall Xr	Role PS	Manufacturer	Route
Date:11/26/ Age:8 YR	02ISR Number Gender:Male	: 4018068-3Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #US0222000			
Outcome Dose SEE NARRATI	Duration VE 5 YR	PT Hyperglycaemia	Report Source Other	Product Adderall	Role PS	Manufacturer	Route
	02ISR Number Gender:Fema	: 4018067-1Report Type:Expedit le I/FU:I	ed (15-DaCompany Repor	t #US0221900			
Outcome Dose Other 15 MG TWICE	Duration A	PT Convulsion	Report Source Other	Product Adderall	Role PS	Manufacturer	Route
DAY	4 YR						

Date:12/02/02ISR Number Age:13 YR Gender:Male	r: 4018460-7Report Type:Direct e I/FU:I	Company Rep	oort #CTU 181952			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged 10MG QD ORAL	Abnormal Behaviour Agitation		Adderall Xr 10mg Shire	PS	Shire	ORAL
	Depression Suicidal Ideation		Effexor Xr	С		
Date:12/04/02ISR Number Age:34 YR Gender:Fema	r: 4019482-2Report Type:Direct ale I/FU:I	Company Rep	oort #CTU 182158			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Death IN MEDICAL	Confusional State		Adderall	PS		
Hospitalization - RECORDS	Delusion					
Initial or Prolonged Other	Hallucination Psychotic Disorder Road Traffic Accident					
Date:12/04/02ISR Number Age:10 YR Gender:Male	r: 4019513-XReport Type:Direct e I/FU:I	Company Rep	oort #CTU 182155			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Required 30MG QD 047	Asthenia		Adderall 30mg	PS		
Intervention to 20MG QD 047	Disorientation		Paxil 20mg	SS		
Prevent Permanent Impairment/Damage	Hallucination Loss Of Consciousness					

		FDA - Adverse	e Event Reporting Syste	em (AER	2S)	
		Freedom O	Of Information (FOI) Re	port		
Date:12/04/02ISR Number: Age:10 YR Gender:Male	: 4019514-1Report Type:Direct I/FU:I	Company Repor	t #CTU 182156			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
	Loss Of Consciousness		Adderall 30mg	PS		ORAL
Intervention to Prevent Permanent Impairment/Damage			Paxil	С		
Date:12/04/02ISR Number: Age:10 YR Gender:Male	: 4019516-5Report Type:Direct I/FU:I	Company Repor	t #CTU 182157			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Required 30MG XR ORAL	Agitation		Adderall 30mg Xr	PS		ORAL
Intervention to DAILY	Asthenia					
Prevent Permanent Impairment/Damage 1 TSP	Dyspnoea Hallucination, Visual		Health Generations Cough Syrup	SS		
	Sleep Disorder Speech Disorder					
Date:12/06/02ISR Number: Age:10.5 YR Gender:Male	: 4020328-7Report Type:Direct I/FU:I	Company Repor	t #CTU 182296			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Abdominal Discomfort Abnormal Behaviour		Generic Ritalin 5 Mg Tab	PS		ORAL
5 MG PO BID	Aggression		Adderall 10mg Tab	SS		ORAL
10 MG PO QD 18 MG PO QD	Decreased Appetite		Concerta 18 Mg Tab	SS		ORAL
10 MG PO QU	Drug Ineffective Educational Problem Headache Hostility Insomnia					

Irritability Pharmaceutical Product Complaint Psychomotor Hyperactivity Pyromania Vomiting Date:12/06/02ISR Number: 4020341-XReport Type:Direct Company Report #CTU 182298 Age: Gender:Male I/FU:I  $\mathbf{PT}$ Report Source Product Role Manufacturer Outcome Route Duration Dose Drug Ineffective Adderall 30mg Daw ΡS Other Daw 30MG, TWICE Pharmaceutical Product DAILY Complaint Adderall 20mg Daw SS Daw 20MG, TWICE DAILY Date:12/11/02ISR Number: 4024834-0Report Type:Expedited (15-DaCompany Report #US0238900 Gender:Female I/FU:I Age: Report Source Role Manufacturer Outcome PTProduct Route Duration Dose Convulsion Health Adderall Xr ΡS 10 MG Professional

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:12/11/02ISR Number: 4024852-2Report Type:Expedited (15-DaCompany Report #US0238800 Age:5 YR Gender:Male I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Duration Dose Other Aggression Other Adderall Xr PS 10 MG Agitation Tenex Crying (Guanfacine): С Emotional Disorder Hostility Date:12/17/02ISR Number: 4027998-8Report Type:Expedited (15-DaCompany Report #US0229601 Aqe:16 YR Gender:Female I/FU:I PTReport Source Role Manufacturer Outcome Product Route Duration Dose Hospitalization -Arthropathy Health Adderall Xr PS 20 MG Initial or Prolonged Impulsive Behaviour Professional Nervousness Company Overdose Representative Date:12/24/02ISR Number: 4033759-6Report Type:Expedited (15-DaCompany Report #US0223100 Age:40 YR Gender:Female I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Abortion Spontaneous Health Adderall PS Complications Of Maternal Professional Exposure To Therapeutic Drugs Maternal Drugs Affecting Foetus Unintended Pregnancy Date:12/24/02ISR Number: 4033761-4Report Type:Expedited (15-DaCompany Report #US0223300 Gender:Male I/FU:I Age: PTReport Source Product Role Manufacturer Route Outcome

Dose

Duration

		Cardiac Failure Chest Pain Cough Vomiting	Consumer	Adderall	PS		
Date:12/30/( Age:3 MON	02ISR Number: Gender:Femal	: 4032719-9Report Type:Direct le I/FU:I	Company Repor	rt #CTU 183545			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 10MG ORAL	Duration	Drug Withdrawal Syndrome		Adderall 10mg Shire	PS	Shire	ORAL
Date:01/03/0 Age:	03ISR Number: Gender:Male	: 4035088-3Report Type:Direct I/FU:I	Company Repor	rt #CTU 183752			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Drug Ineffective Pharmaceutical Product Complaint		Adderall 5mg Amphetamine/Dextroam	PS SS		

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:01/06/03ISR Number: 4037039-4Report Type:Direct Company Report #CTU 183943 Gender:Male Age:13 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Other Drug Ineffective Generic Adderal 10mg PS ORAL 2 AM 1T PM Nausea ORAL; 4MO Pharmaceutical Product -GENERIC Complaint Date:01/08/03ISR Number: 4040701-0Report Type:Expedited (15-DaCompany Report #US0240200 Age:4 YR Gender: I/FU:I PTRole Manufacturer Report Source Product Route Outcome Dose Duration Petit Mal Epilepsy Adderall Xr Other Health PS Speech Disorder Professional Company Representative Date:01/13/03ISR Number: 4041208-7Report Type:Direct Company Report #CTU 184295 Age:10 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Dyskinesia Adderall Xr 10mg Po Tic PS ORAL Oam 10MG PO QAM Date:01/13/03ISR Number: 4041244-0Report Type:Direct Company Report #CTU 184327 Age:16 YR Gender:Male I/FU:I Outcome  $\mathbf{PT}$ Report Source Product Role Manufacturer Route Duration Dose Other Dyskinesia Adderal 10mg PSORAL 1 X A DAY Respiratory Disorder ORAL

Date:01/28/03ISR Number: 4048783-7Report Type:Expedited (15-DaCompany Report #US0300800 Age:8 YR Gender:Male I/FU:I

Outcome	РТ	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization - 10 MG	Convulsion	Other	Adderall Xr	PS	
Initial or Prolonged	Electroencephalogram Abnormal Tremor		Vitamins	С	

Date:01/28/03ISR Number: 4048785-0Report Type:Expedited (15-DaCompany Report #US0301600 Age:7 YR Gender:Male I/FU:I

Outcome		РТ	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Life-Threater 10 MG 6 DOSES	-	Cyanosis	Other	Adderall Xr	PS		
Hospitalizati	ion -	Difficulty In Walking		Coumadin (Warfarin			
Initial or Pr	rolonged	Dizziness		Sodium)	С		
		Headache		Lanoxin (Digoxin)	С		
		Hypoxia		Captopril	С		
		Malaise Respiratory Distress Syncope Vomiting		Lasix (Furosemide)	С		

Freedom Of Information (FOI) Report

Date:01/28/03ISR Number: 4048991-5Report Type:Expedited (15-DaCompany Report #US0300400 Age:8 YR Gender:Female I/FU:I

Duration	РТ	Report Source	Product	Role	Manufacturer	Route
	Abnormal Behaviour	Other	Adderall Xr	PS		
2 1101	Aggression Anger Condition Aggravated		Claritin (Loratidine) Allegra	С		
	Hostility Staring Stupor		(Fexofenidine Hydrochloride) Nubulizer	C C		
		dited (15-DaCompany Re	port #US0301000			
	PT	Report Source	Product	Role	Manufacturer	Route
Duration	Completed Suicide Injury Asphyxiation	Health Professional Company Representative	Adderall	PS		
		dited (15-DaCompany Re	port #US0301700			
Duration	PT	Report Source	Product	Role	Manufacturer	Route
Duración	Apallic Syndrome	Health	Adderall	PS		
	Arrhythmia Cardiac Arrest Cardiac Failure Congestive Cardiomyopathy Drug Screen Positive Medication Error	Professional				
	03ISR Number Gender:Male Duration 03ISR Number	Duration Abnormal Behaviour 2 MON Aggression Anger Condition Aggravated Hostility Staring Stupor 03ISR Number: 4049232-5Report Type:Expect Gender:Male I/FU:I PT Duration 03ISR Number: 4050182-9Report Type:Expect Gender:Female I/FU:I PT Duration 03ISR Number: 4050182-9Report Type:Expect Gender:Female I/FU:I PT Duration Apallic Syndrome Arrhythmia Cardiac Arrest Cardiac Failure Congestive Cardiomyopathy Drug Screen Positive	Duration Abnormal Behaviour 2 MON Aggression Anger Condition Aggravated Hostility Staring Stupor 03ISR Number: 4049232-5Report Type:Expedited (15-DaCompany Re Gender:Male I/FU:I PT Report Source Duration Completed Suicide Injury Asphyxiation Company Representative 03ISR Number: 4050182-9Report Type:Expedited (15-DaCompany Re Gender:Female I/FU:I PT Report Source Company Representative 03ISR Number: 4050182-9Report Type:Expedited (15-DaCompany Re Gender:Female I/FU:I PT Report Source Apallic Syndrome Health Arrhythmia Cardiac Arrest Cardiac Failure Congestive Cardiomyopathy Drug Screen Positive	Duration     Abnormal Behaviour     Other     Adderall Xr       2     MON     Aggression Anger     Claritin (Loratidine)       Anger     Claritin (Loratidine)     Allegra       Anger     Condition Aggravated Hostility Staring     Allegra       Mostility     Staring     Allegra       Voter     Hostility     (Fexofenidine)       Staring     Hydrochloride)     Nubulizer       03ISR Number:     4049232-5Report Type:Expedited (15-DaCompany Report #US0301000       Gender::Male     I/FU:I     PT       Puration     Report Source     Product       Completed Suicide Injury Asphyxiation     Health Professional Company Representative     Adderall       03ISR Number:     4050182-9Report Type:Expedited (15-DaCompany Report #US0301700     Product       03ISR Number:     Ho50182-9Report Type:Expedited (15-DaCompany Report #US0301700     Professional Company Representative       03ISR Number:     4050182-9Report Type:Expedited (15-DaCompany Report #US0301700     Professional Cardiac Arrest Cardiac Arrest Cardiac Arrest Cardiac Arrest Cardiac Arrest Cardiac Arrest Cardiac Arrest Cardiac Failure Congestive Cardiac Spathy Drug Screen Positive     Professional	DurationAbnormal BehaviourOtherAdderall XrPS2MONAggression Anger Condition Aggravated Hostility Staring StuporClaritin (Loratidine) C Allegra (Pexofenidine Bydrochloride) C OutlierC03ISR Number:4049232-5Report Type:Expedited (15-DaCompany Report #US0301000 I/FU:IC03ISR Number:PT Completed Suicide Injury AsphyxiationReport Source Product Professional Company RepresentativeProductRole03ISR Number:4050182-9Report Type:Expedited (15-DaCompany Report #US0301700 Gender:FemalePT Professional Company RepresentativeRole03ISR Number:4050182-9Report Type:Expedited (15-DaCompany Report #US0301700 Gender:FemalePT Report SourceProductRole03ISR Number:4050182-9Report Type:Expedited (15-DaCompany Report #US0301700 Company RepresentativePSProfessional Company RepresentativePS03ISR Number:4050182-9Report Type:Expedited (15-DaCompany Report #US0301700 Company RepresentativePSPS03ISR Number:4050182-9Report Type:Expedited (15-DaCompany Report #US0301700 Company RepresentativePSPS03ISR Number:Arrhythmia Cardiac Arrest Cardiac Arrest Cardiac ArrestProfessional Cardiac Arrest Cardiac Arrest Cardiac Arrest Cardiac Arrest Cardiac MarketProfessional Cardiac Arrest Cardiac Market Drug Screen PositivePS	DurationAbnormal BehaviourOtherAdderall XrPS2MON Aggression AngerAggression Anger Condition Aggravated Hostility Staring StupperClaritin (Loratidine) Allegra Hydrochloride)C03ISR Number:tot49232-5Report Type:Expedited (15-DaCompany Report #US0301000 Gender:MaleCDurationPT Completed Suicide Injury AsphyxiationReport Source Professional Company RepresentativeRole Manufacturer03ISR Number:4050182-9Report Type:Expedited (15-DaCompany Report #US0301700 Gender:FemaleRole Manufacturer03ISR Number:4050182-9Report Type:Expedited (15-DaCompany Report #US0301700 Company RepresentativeRole Manufacturer03ISR Number:4050182-9Report Type:Expedited (15-DaCompany Report #US0301700 Company RepresentativeRole Manufacturer03ISR Number:PT Report SourceRole Manufacturer03ISR Number:PT Report SourceRole Manufacturer03ISR Number:4050182-9Report Type:Expedited (15-DaCompany Report #US0301700 Company RepresentativeProfessional Company Representative03ISR Number:4050182-9Report Type:Expedited (15-DaCompany Report #US0301700 Company RepresentativeRole Manufacturer03ISR Number:PT Report SourceProductRole Manufacturer03ISR Sumper:PT Report SourceProfessional Company Report SourceProfessional Report Source03ISR Sumper:PT Report SourceRole ArchiveRole Manufacturer03ISR Sumper:PT Report SourceProfessiona

Date:02/04/ Age:12 YR	03ISR Number Gender:Fema	: 4051015-7Report Type:Direct le I/FU:I		Company Repor	t #CTU 185866			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other 2 PO BID	24240201	Irritability			Adderall 10 Mg	PS		ORAL
		Pharmaceutical Product Complaint Psychomotor Hyperactivity			Amphetamine	SS		
Date:02/04/ Age:12 YR	03ISR Number Gender:Male	: 4051675-0Report Type:Direct I/FU:I		Company Repor	t #CTU 185932			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other 30MG XR	3 DAY	Agitation			Adderall Xr	PS		
		Anorexia Insomnia Pharmaceutical Product Complaint						

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:02/04/03ISR Number: 4052796-9Report Type:Expedited (15-DaCompany Report #US0301500 Gender:Female Aqe:20 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Agitation Health Adderall PS 5 MG BID Initial or Prolonged Bipolar Ii Disorder Professional Adderall SS 20 MG BID Confusional State Hypomania Mania Date:02/05/03ISR Number: 4052355-8Report Type:Direct Company Report #CTU 186004 Gender: I/FU:I Age: PTReport Source Role Manufacturer Product Route Outcome Dose Duration Medication Error Adderal Xr 10mg Shire PS Shire Adderal Xr 20mg Shire SS Shire Date:02/12/03ISR Number: 4055716-6Report Type:Direct Company Report #CTU 186528 Aqe:34 YR Gender:Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Death Accident Adderall PS IN MEDICAL Hospitalization -Confusional State RECORDS Initial or Prolonged Psychotic Disorder Other Date:02/12/03ISR Number: 4056493-5Report Type:Expedited (15-DaCompany Report #US0302500 Age:14 YR Gender:Male I/FU:I PTReport Source Product Role Manufacturer Outcome Route Dose Duration

Other 30 MG	Abnormal Behaviour	Consumer	Adderall Xr	PS	
	Anger Hostility Physical Abuse	Other			
Date:02/12/03ISR Nu Age:11 YR Gender:	mber: 4057308-1Report Type:Ex Female I/FU:I	pedited (15-DaCompany Re	eport #US-02-389-01		
Outcome Dose Durati	PT	Report Source	Product	Role Manufacturer	Route
Other 10 MG	Convulsion	Health	Adderall Xr	PS	
10 110		Professional			
Date:02/13/03ISR Nu Age:23 YR Gender: Outcome Required Intervention to Prevent Permanent Impairment/Damage	mber: 4056509-6Report Type:Di Female I/FU:I PT Anorexia Asthenia Depression Dry Mouth Menstruation Irregular Neutropenia Red Blood Cell Count Decreased	rect Company Re	eport #CTU 186613		
22-Aug-2005 10:34 .	White Blood Cell Count				

Freedom Of Information (FOI) Report

Decreased

Dose	Duration		Report Source	Product	Role	Manufacturer	Route
	Duración			Adderall	PS		ORAL
10 MG ORAL				Seroquel	SS		ORAL
100 MG ORAL				-			
	03ISR Number Gender:Fema	: 4062084-2Report Type:Expedit le I/FU:I	ed (15-DaCompany Repor	t #US0302700			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Neurosis Tremor	Other	Adderall	PS		
Age: Outcome Dose	03ISR Number Gender:Male Duration	PT	Report Source	Product		Manufacturer	Route
Other 20 MG		Convulsion	Foreign	Adderall Xr	PS		
20 143			Health Professional	Paxil(Paroxetine Hydrochloride) 20 Mg Risperdal			
				(Risperidoen)	С		
Date:02/24/ Age:8 YR	03ISR Number Gender:Male	: 4059790-2Report Type:Direct I/FU:I	Company Repor	t #CTU 187213			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threat Required ONCE DAILY	ening	Abnormal Behaviour Agitation		Adderal Xr 15 Mg. Shire Us, Inc.	PS	Shire Us, Inc.	
Intervention Prevent Perr Impairment/M	manent	Disorientation Heart Rate Increased Self Injurious Behaviour Suicidal Ideation					

Date:02/24/0 Age:	)3ISR Number: Gender:Male	: 4060004-8Report Type:Direct I/FU:I	Company Report	t #CTU 187171		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other ONE BID 6D/W		Nausea		Adderall	PS	
	)3ISR Number: Gender:Femal	: 4066342-7Report Type:Expedito le I/FU:I	ed (15-DaCompany Report	t #US0304900		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 30 MG DAILY		Aggression	Other	Adderall Xr	PS	
4-5 SHOTS		Homicidal Ideation Psychotic Disorder		Alcohol (Nos)	SS	
		: 4066344-0Report Type:Expedite I/FU:I	ed (15-DaCompany Repor <sup>.</sup>	t #US0303300		
Outcome		PT Emotional Disorder Hallucination Insomnia				
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Freedom Of Information (FOI) Report

		Nervousness					
Dose	Duration		Report Source	Product	Role	Manufacturer	Route
DOSE	Duración		Other	Adderall Xr	PS		
SEE NARRATIV	Æ						
	)3ISR Number Gender:Fema	: 4069419-5Report Type:Exped: le I/FU:F	ited (15-DaCompany Rep	port #US0301701			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death SEE IMAGE	Duración	Amphetamines Positive	Health	Adderall	PS		
		Apallic Syndrome Cardiac Arrest Cardiac Failure Congestive Cardiomyopathy Circulatory Collapse Drug Screen Positive Nodal Arrhythmia Right Ventricular Failure Ventricular Tachycardia	Professional				
	3ISR Number Gender:Male	: 4070563-7Report Type:Exped: I/FU:I	ited (15-DaCompany Rej	port #US0306800			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death		Completed Suicide	Other	Adderall Xr	PS		
30 MG DAILY		Condition Aggravated Gun Shot Wound Major Depression		Adderall Xr Clonidine	SS C		
	)3ISR Number Gender:Fema	: 4070969-6Report Type:Exped: le I/FU:I	ited (15-DaCompany Rej	port #US0303500			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route

Dose Duration

Hospitalization - 20 MG DAILY	Cerebrovascular Accident	Consumer	Adderall	PS	
Initial or Prolonged			Atenolol	С	
			Norvasc (Amiodipine)	C	
			Aggrenox (Sic)	C	
			Spironolacytone	C	
Date:03/07/03ISR Numl Age:49 YR Gender:Fe	per: 4072407-6Report Type:Exp emale I/FU:I	edited (15-DaCompany R	eport #US0306300		
Outcome Dogo Duration	PT	Report Source	Product	Role Manufacturer	Route
Outcome Dose Duration	ı	-			Route
Dose Duration		Report Source Consumer	Product Adderall Xr	Role Manufacturer PS	Route
	n Raynaud'S Phenomenon	-	Adderall Xr		Route
Dose Duration	n Raynaud'S Phenomenon Retching	-	Adderall Xr Wellbutrin		Route
Dose Duration	n Raynaud'S Phenomenon Retching Systemic Lupus	-	Adderall Xr Wellbutrin (Bupropion	PS	Route
Dose Duration	Raynaud'S Phenomenon Retching Systemic Lupus Erythematosus	-	Adderall Xr Wellbutrin		Route
Dose Duration	n Raynaud'S Phenomenon Retching Systemic Lupus	-	Adderall Xr Wellbutrin (Bupropion	PS	Route

Freedom Of Information (FOI) Report

Date:03/07/03ISR Number: 4072683-XReport Type:Expedited (15-DaCompany Report #US0305700 Age:42 YR Gender:Female I/FU:I

Outcome Dose	Duratio		РТ	Report Source	Product	Role	Manufacturer	Route
			Diabetes Mellitus	Consumer	Adderall Xr	PS		
10 MG DAILY	4	MON			Insulin Pump	С		

Date:03/11/03ISR Number: 4074653-4Report Type:Expedited (15-DaCompany Report #US0303900 Age:36 YR Gender:Female I/FU:I

4						
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Death 30 MG AM, 15		Abdominal Pain Upper	Other	Adderall	PS	
		Anoxia				
PM 200MG AT		Asthenia		Elavil	SS	
		Cardiac Arrest				
NIGHT		Encephalopathy Nausea Subarachnoid Haemorrhage				
	3ISR Number Gender:Male	: 4076414-9Report Type:Direct I/FU:I	Company Report	t #CTU 189033		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other 5MG PO QAM	Duration	Abnormal Behaviour		Adderall 5mg Generic	PS	ORAL
		Disturbance In Attention Pharmaceutical Product Complaint				

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat	Duration ion -	Hypertension	Health	Aderall Xr	PS		
10 MG Initial or P	rolonged		Professional				
	3ISR Number Gender:Male	r: 4078781-9Report Type:Exped. e I/FU:I	ited (15-DaCompany R	eport #US0307500			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 5 MG	Duración	Facial Palsy	Health	Aderall Xr	PS		
5 110			Professional				
	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Outcome Dose	Duration					Manufacturer	Route
Other 10 MG TO 20		Alanine Aminotransferase	Consumer Other	Adderall Xr	PS		
MG		Increased	Other				
300 MG	9 MON	Hepatic Function Abnormal		Isoniazid	SS		
		Hypertension Irritability		Vitamin B6 Aceon(Perindopril	С		
		Nervousness		Erbumine) Tiazac(Diltiazem	С		
				Hydrochloride)	С		
				Hydrochlorothiazide	С		
				Zoloft(Sertraline Hydrochloride)	С		
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Freedom Of Information (FOI) Report

Proventil Inhaler C

1/03ISR Numl Gender:Fe	nber: 4078435-9Report Type: Female I/FU:I	Direct Company Re	port #CTU 189264			
Duratio	PT	Report Source	Product	Role	Manufacturer	Route
Duració	Menorrhagia		Seroquel	PS		ORAL
ion to	Menstruation Irregular		Adderal	SS		ORAL
ermanent t/Damage	Pain Rash Tinnitus					
1/03ISR Numl Gender:Fe		Expedited (15-DaCompany Re	port #US0305800			
Duratio	PT	Report Source	Product	Role	Manufacturer	Route
zation - r Prolonged	Paranoia Psychotic Disorder Schizophrenia	Other	Adderall	PS		
1/03ISR Numl Gender:Ma		Expedited (15-DaCompany Re	port #US0306900			
Duratio	PT	Report Source	Product	Role	Manufacturer	Route
zation - TIVE	Atrial Fibrillation	Health	Adderall Xr	PS		
r Prolonged TIVE	1	Professional	Adderall Xr	SS		
ion to ermanent		Company Representative	"Cocktail" Of Other Medications Zyprexa (Olanzepine) Depakote (Divalproex	C C		
			Medications Zyprexa (Olanzepine)			

Outcome		PT	Report Source	Product	Pole	Manufacturer	Route
Dose	Duration	<u>F</u> I	Report Source	Product	KOIE	Manuracturer	Route
Other 20 MG		Supraventricular	Consumer	Adderall Xr	PS		
		Tachycardia	Company Representative				
Date:03/21/ Age:9 YR	03ISR Number Gender:Fema	r: 4081995-5Report Type:Ex ale I/FU:I	xpedited (15-DaCompany Re	eport #US0308700			
			xpedited (15-DaCompany Re Report Source	eport #US0308700 Product	Role	Manufacturer	Route
Age:9 YR		ale I/FU:I			Role	Manufacturer	Route
Age:9 YR Outcome Dose Other	Gender:Fema	Ale I/FU:I PT Memory Impairment			Role PS	Manufacturer	Route
Age:9 YR Outcome Dose	Gender:Fema	Ale I/FU:I PT Memory Impairment	Report Source	Product		Manufacturer	Route
Age:9 YR Outcome Dose Other	Gender:Fema	Ale I/FU:I PT Memory Impairment	Report Source	Product Adderall Xr	PS	Manufacturer	Route
Age:9 YR Outcome Dose Other 15 MG DAILY	Gender:Fema	Ale I/FU:I PT Memory Impairment	Report Source	Product Adderall Xr	PS	Manufacturer	Route
Age:9 YR Outcome Dose Other 15 MG DAILY	Gender:Fema	Ale I/FU:I PT Memory Impairment Stereotypy	Report Source	Product Adderall Xr	PS	Manufacturer	Route

Freedom Of Information (FOI) Report

Date:03/21/03ISR Number: 4081997-9Report Type:Expedited (15-DaCompany Report #US0307100 Age:46 YR Gender:Female I/FU:I

							,
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 3 MON	Duración	Amblyopia	Health	Adderall	PS		
3 MON		Burning Sensation Oedema Peripheral Peripheral Vascular Disorder Rash Thrombosis	Professional	Performance Enhancers: "Parrillo Performance" Primrose Oil Essential Vitamin Formula Muscle Amino Formula Joint Formula Max Endurance Formula High Protein Vanilla Mineral Electrolyte Formula Cap Tri	С С С С С С С С С С С С		
	)3ISR Number Gender:Male	r: 4079301-5Report Type:Direct I/FU:I	Company Repor	rt #CTU 189353			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 20MG 1 ORAL		Abnormal Behaviour		Adderall Xl 20mg	PS		ORAL
5MG 1		Asocial Behaviour		Adderall 5mg	SS		
		Emotional Disorder					
	)3ISR Number Gender:Femal	: 4079694-9Report Type:Direct ale I/FU:I	Company Repor	ct #CTU 189343			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Drug Effect Decreased Pharmaceutical Product		Adderal Xr 20mg Shire	PS	Shire	ORAL
2 CAPS 1 CAP		Complaint					
AT 3PM ORAL		Comptatile					

	Number: 4095435-3Report Type:P r: I/FU:I	'eriodic Company	Report #USA030228712		
Outcome Dose Dura	PT tion	Report Source	Product	Role Manufacturer	Route
	Abnormal Behaviour Aggression	Health Professional	Strattera (Atomoxetine		
			Hydrochloride)	PS	
0.5 MG/DAY			Adderall	SS	
	Number: 4083479-7Report Type:E r:Male I/FU:I	Expedited (15-DaCompany	Report #US0306900		
		Expedited (15-DaCompany	Report #US0306900		
Age: Gende:	r:Male I/FU:I	Expedited (15-DaCompany	Report #US0306900		
Age: Gende: Outcome	r:Male I/FU:I PT		Report #US0306900		
Age: Gende:	r:Male I/FU:I PT Dacryostenosis Acquired		Report #US0306900		
Age: Gende: Outcome	r:Male I/FU:I PT Dacryostenosis Acquired Granuloma		Report #US0306900		
Age: Gende: Outcome	r:Male I/FU:I PT Dacryostenosis Acquired Granuloma Hordeolum		Report #US0306900		
Age: Gende: Outcome	r:Male I/FU:I PT Dacryostenosis Acquired Granuloma Hordeolum Lacrimation Decreased		Report #US0306900		
Age: Gende: Outcome	r:Male I/FU:I PT Dacryostenosis Acquired Granuloma Hordeolum Lacrimation Decreased Libido Increased		Report #US0306900		
Age: Gende: Outcome	r:Male I/FU:I PT Dacryostenosis Acquired Granuloma Hordeolum Lacrimation Decreased Libido Increased Pharmaceutical Product		Report #US0306900		
Age: Gende: Outcome	r:Male I/FU:I PT Dacryostenosis Acquired Granuloma Hordeolum Lacrimation Decreased Libido Increased		Report #US0306900		

Freedom Of Information (FOI) Report

С

Ativan

		Testicular Pain					
Daga	Duration		Report Source	Product	Role	Manufacturer	Route
Dose 30 MG TID	Duracion		Consumer	Adderall	PS		
				Generic Adderall	SS		
30 MG TID							
	)3ISR Number Gender:Fema	: 4086090-7Report Type:Direct le I/FU:I	Company Repor	rt #CTU 190018			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Dizziness		Adderall 10mg Po	PS		ORAL
10MG PO X1		Dysuria Fall Medication Error					
Date:04/03/0 Age: Outcome Dose	)3ISR Number Gender:Male Duration	: 4084158-2Report Type:Expedi I/FU:I PT	ted (15-DaCompany Repor Report Source	rt #US-GLAXOSMITHKLINE- Product		91A Manufacturer	Route
Other UNKNOWN		Hallucination	Consumer	Paxil	PS	Glaxosmithkline	
UNKNOWN		Psychotic Disorder		Adderall	SS		
Date:04/08/( Age:36 YR		: 4092127-1Report Type:Expedi le I/FU:I	ted (15-DaCompany Repor	rt #2003UW03066			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Death 200 MG HS PO		Abdominal Pain Upper	Health	Elavil	PS		ORAL
Hospitalizat	cion -	Anoxic Encephalopathy Cardiac Arrest Drug Interaction	Professional	Adderall Toradol Effexor-Xr	SS C C		

Subarachnoid Haemorrhage

Methadone C

Date:04/08/03ISR Number: 4092154-4Report Type:Expedited (15-DaCompany Report #US0311700 Age:22 YR Gender:Male I/FU:I

Outcome	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat SEE NARRATIV	ion -	Bipolar Disorder	Health	Adderall	PS		
Initial or F		Delusion Depression Drug Ineffective Drug Tolerance Fatigue Hallucination Insomnia Overdose Paranoia Psychotic Disorder Speech Disorder	Professional	Lithium Celexa (Citalopram Hydrobromide)	C		
	3ISR Number Gender:Male	: 4088650-6Report Type:Direct I/FU:I	Company Repor	t #CTU 190597			
Outcome		PT Dyskinesia Eyelid Function Disorder					
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Freedom Of Information (FOI) Report

		Tic					
Dose	Duration		Report Source	Product	Role	Manufacturer	Route
10MG	Duración			Adderall Xr 10 Mg Po Qd Adderall	PS C		
				Addetail	C		
	BISR Number: Gender:Male	4088667-1Report Type:Direct I/FU:I	Company Repor	rt #CTU 190575			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Bipolar Disorder		Adderal Generic Brand 10mg	PS		
10MG ONCE OTHER							
	3ISR Number: Gender:Femal	4112506-3Report Type:Periodi Le I/FU:I	c Company Repor	rt #US0300500			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizati 10 MG DAILY		Psychotic Disorder	Literature	Adderall	PS		
Initial or Pi	rolonged		Consumer				
	3ISR Number: Gender:Male	4112507-5Report Type:Periodi I/FU:I	c Company Repor	rt #US0222400			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizati 40 MG AM		Hypertension	Health	Adderall	PS		
Initial or Pr	rolonged		Professional				

Date:04/14/03ISR Num Age:18 YR Gender:M	ber: 4112508-7Report Type:Per ale I/FU:I	iodic Company Re	eport #US0220600		
Outcome Dose Duratio	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - SEE NARRATIVE	Drug Abuser	Other	Adderall	PS	
Initial or Prolonged	Psychotic Disorder				
Date:04/15/03ISR Num Age:41 YR Gender:F	ber: 4095428-6Report Type:Exp emale I/FU:I	edited (15-DaCompany Re	eport #US0311100		
Outcome Dose Duratio	PT n	Report Source	Product	Role Manufacturer	Route
Other 10 MG X 3 IN	Angiopathy	Health	Adderall Xr	PS	
AM 3	Cerebral Ischaemia MON	Professional			
	Eye Disorder Transient Ischaemic Attack Visual Acuity Reduced	Other			
Date:04/16/03ISR Num Age:17 YR Gender:F	ber: 4097262-XReport Type:Exp emale I/FU:I	edited (15-DaCompany Re	eport #US0311500		
Outcome	PT				
Hospitalization - Initial or Prolonged	Anxiety Asthenia Dizziness Hypoaesthesia				
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Freedom Of Information (FOI) Report

		Hyporeflexia Hypoventilation Paralysis	Report Source	Product	Role	Manufacturer	Route
Dose	Duration					handraddarer	nouce
20 MG ONE			Health	Adderall Xr	PS		
TIME			Professional				
TIME							
	3ISR Number Gender:Male	: 4097278-3Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	rt #US0311300			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 20 MG	Duración	Lymphadenopathy	Other	Adderall Xr	PS		
20 MG		Pain In Extremity Red Blood Cell Sedimentation Rate Increased Tenderness					
	)3ISR Number Gender:Male	: 4097284-9Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	rt #US0308100			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
	242402011	Medication Tampering	Health	Adderall Xr	PS		
20 MG		Treatment Noncompliance	Professional				
		: 4098127-XReport Type:Expedi le I/FU:I	ted (15-DaCompany Repo	rt #US0311800			
Outcome	Decest '	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 10 MG HEN 30	Duration	Depersonalisation	Other	Adderall Xr	PS		
MC	2 1/011	Homicidal Ideation					
MG	3 MON			Lexatro	С		

		Personality Disorder Suicidal Ideation		Zyprexa	С		
	/03ISR Number Gender:Male	r: 4098128-1Report Type:Expe e I/FU:F	dited (15-DaCompany Re	eport #US-03-082-01			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threat 10 MG		Hypertension	Health	Adderall Xr	PS		
Hospitaliza Initial or		White Blood Cell Count Abnormal	Professional				
	/03ISR Number Gender:Male	r: 4098129-3Report Type:Expe e I/FU:I	dited (15-DaCompany Re	eport #US-03-120-00			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Abnormal Behaviour	Other	Adderall Xr	PS		
5 MG	3 WK	Aggregation		Colorro (Citolorrom			
		Aggression Hostility Injury Scratch		Celexa (Citalopram Hydrobromide)	С		

Self Injurious Behaviour

			FDA – Adve	erse Event Reporting Syst	tem (AER	נs )	
			Freedc	om Of Information (FOI) F	Report		
Date:04/18, Age:8 YR	/03ISR Number Gender:Fema	: 4096274-XReport Type:Direct ale I/FU:I	Company Re	eport #CTU 191267			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	2 42 6 - 2	Unevaluable Event		Adderal Tabs 5mg (Generic)	PS		
Date:04/25, Age:	/03ISR Number Gender:Male	: 4102951-4Report Type:Expedit I/FU:I	ted (15-DaCompany Re	port #US0312900			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other SEE IMAGE	Duration 2 YR	Aggression Dyspnoea Hallucination, Tactile Hallucination, Visual Hostility Muscle Twitching Nervousness Overdose Paranoia Restlessness Skin Ulcer Thinking Abnormal Tic Tourette'S Disorder Weight Decreased	Other	Adderall	PS		
Date:04/29/ Age:	/03ISR Number Gender:Male	: 4101982-8Report Type:Direct I/FU:I	Company Re	eport #CTU 191807			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Abnormal Behaviour		Adderall Xr 30 Mg		Shire	

Outcome	Duratio	PT	Report Source	Product	Role Manufacturer	Route
Dose Other	Duratio	n Abdominal Pain Affect Lability		Generic Adderal 10mg	PS	
1 QD		Crying Pharmaceutical Produ Complaint	act			
Date:04/30 Age:15 YR			pe:Expedited (15-DaCompany Re	eport #US0313600		
Age:15 YR Outcome	Gender:M	ale I/FU:I PT	pe:Expedited (15-DaCompany Ro Report Source	eport #US0313600 Product	Role Manufacturer	Route
Age:15 YR	Gender:M Duratio	ale I/FU:I PT			Role Manufacturer PS	Route

Freedom Of Information (FOI) Report

Date:04/30/03ISR Number: 4106068-4Report Type:Expedited (15-DaCompany Report #US0313700 Age:22 YR Gender:Female I/FU:I

Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Adrenal Disorder	Other	Adderall Xr	PS		
40 MG		Bundle Branch Block Right					
SINCE IT CA		Syncope Tachycardia		Zoloft(Sertraline Hydrochloride) Sonata (Zaleplon)	C C		
Date:05/05/( Age:	)3ISR Number Gender:Male	: 4107403-3Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #US0313100			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duration	Agranulocytosis Upper Respiratory Tract Infection	Health Professional	Adderall	PS		
Date:05/05/( Age:9 YR	)3ISR Number Gender:Male	: 4107408-2Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #US0313300			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10 MG TWICE		Electrocardiogram Qt	Health	Adderall	PS		
DAY	A	Corrected Interval	Professional				
DAI		Prolonged Syncope					
Date:05/08/( Age:	)3ISR Number Gender:	: 4108886-5Report Type:Direct I/FU:I	Company Repor	t #USP 081097			
Outcome	Dunchion	РТ	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Medication Error		Adderal	PS	Richwood	

	3ISR Number: Gender:	4109829-0Report 7 I/FU:I	Type:Direct	Company 1	Report #USP 081110			
Outcome Dose	Duration	PT	Repor	t Source	Product	Role	Manufacturer	Route
Other	Duración	Medication Error			Adderal 10mg Adderal 20mg	PS SS	Ric	
	3ISR Number: Gender:Male	: 4119096-XReport ] I/FU:I	Type:Periodic	Company I	Report #US0301400			
Outcome	Duration	PT	Repor	t Source	Product	Role	Manufacturer	Route
Dose Disability 30 MG	Duración	Psychotic Disorder	c Other		Adderall Xr	PS		
	3ISR Number: Gender:Male	4111983-1Report T I/FU:I	Type:Expedited (15	-DaCompany	Report #SUS1-2003-0000	)2		
		—		-DaCompany 1 t Source	Report #SUS1-2003-0000 Product		Manufacturer	Route

			FDA - Adverse	e Event Reporting Syste	m (AER	RS )	
				Of Information (FOI) Re		,	
Date:05/13/ Age:	03ISR Number: Gender:Male	: 4112953-XReport Type:Direct I/FU:I	Company Repor	rt #CTU 192880			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitaliza Initial or :		Abdominal Pain Dyspnoea Erythema		Adderall	PS		
	03ISR Number: Gender:Male	: 4114132-9Report Type:Direct I/FU:I	Company Repor	rt #CTU 193193			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Paraesthesia		Adderall Xr 10 Mg Shire	PS	Shire	ORAL
10 MG QD OR.	AL						
Date:05/21/ Age:52 YR Outcome Dose	03ISR Number: Gender:Male Duration	: 4115973-4Report Type:Expedit I/FU:I PT	ted (15-DaCompany Repor Report Source	rt #SUS1-2003-00004 Product	Role	Manufacturer	Route
Other	Duración	Abnormal Behaviour Aggression Mental Disorder Psychotic Disorder	Health Professional	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,			
30 MG 1				Dextroamphetamine	PS		
XDAY:QD,							
Date:05/21/ Age:7 YR	03ISR Number: Gender:Male	: 4118086-0Report Type:Direct I/FU:I	Company Repor	rt #CTU 193535			
Outcome	Direction	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Crying		Adderall	PS		ORAL
12.5MG PO QAM[ TOOK I	Т	Headache					

FOR 1 MONTH 2	Pharmaceutical Product				
FOR I MONIH Z	Complaint				
1/2 YEARS					
AGO] 1 MON	ſ				
Date:05/22/03ISR Number Age:9 YR Gender:Male	: 4116082-0Report Type:Exped	lited (15-DaCompany Rep	ort #SUSI-2003-00010		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged	Abnormal Behaviour Psychotic Disorder	Consumer Other	Adderall (Amphetamine Aspartate, Amphetamine Sulfate,		
5 MG,			Dextroamphetamine	PS	ORAL
1X/DAY:QD,					
ORAL; 7.5 MG,					
1X/DAY:QD,					
ORAL; 2.5 MG,			Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,		ODAL
10 MG,			Dextroamphetamine	SS	ORAL
1X/DAY:QD,					
ORAL					

Freedom Of Information (FOI) Report

Dextroamphetamine

Date:06/05/03ISR Number: 4125882-2Report Type:Expedited (15-DaCompany Report #SUSI-2003-00017 Age:54 YR Gender:Male I/FU:I

Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other		Supraventricular Tachycardia Syncope	Health Professional	Adderall Family (Amphetamine Aspartate, Amphetamine Suflate, Dextroamphetamine	PS		
15 MG,				-			

1X/DAY: QD,

Date:06/06/03ISR Number: 4126062-7Report Type:Expedited (15-DaCompany Report #SUSI-2003-00039 Age:44 YR Gender:Female I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Disability	Duracion	Dystonia Emotional Disorder	Health Professional	Adderall(Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine	PS		ORAL
20 MG,				Dexeroampriceamine	10		UICAL
3X/DAY: TID,							
ORAL							
				Elavil (Amitriptyline Hydrochloride)	С		
	3ISR Number Gender:Fema	: 4126063-9Report Type:Expedit le I/FU:I	ed (15-DaCompany Repor	t #SUSI-2003-00040			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Temporal Lobe Epilepsy	Consumer Other	Adderall Family(Amphetamine Sulfate,			

				Saccharate,	PS		
10 MG,							
2X/DAY:BID	,						
				Trileptal Novartis (Oxacarbazepine)	С		
				Oral Contraceptive Nos (Oral Contraceptive Nos)	С		
Date:06/09 Age:	/03ISR Number Gender:Male	r: 4126078-OReport Type:Direc e I/FU:I	t Company Re	eport #CTU 195267			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duracion	Insomnia Pharmaceutical Product		Generic Adderall 10mg	PS		
1 Q AM 1/2	Q	Pllatinaceuticat fioduce		Toura	Fυ		
PM	1 MOI	Complaint N					
Date:06/12 Age:7 YR	/03ISR Numbe: Gender:Male	r: 4127753-4Report Type:Direc e I/FU:I	t Company Re	eport #CTU 195672			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Pharmaceutical Product Complaint		Generic Adderall (Eon)	PS	Eon	ORAL
7.5 MG BID	PO 3 MOI						
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			FDA - Adverse	e Event Reporting Syste	em (AERS)	
			Freedom C	Of Information (FOI) Re	port	
Date:06/13/ Age:9 YR	03ISR Number Gender:Male	r: 4128922-XReport Type:Direct e I/FU:I	Company Repor	rt #CTU 195747		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other 10MG TID		Drug Ineffective Pharmaceutical Product		Adderall 10mg	PS	ORAL
		Complaint				
	03ISR Number Gender:Fema	: 4129396-5Report Type:Direct ale I/FU:I	Company Repor	rt #CTU 195803		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Other 30MG BID	Duración	Ear Pain		Adderall	PS	ORAL
DAILY ORAL		Facial Pain				
70MG DAILY		Gingival Disorder		Ritalin	SS	ORAL
		Hyperacusis				
ORAL		Hypoaesthesia Mastication Disorder Mobility Decreased Muscle Spasms Myalgia Pain In Jaw Paraesthesia Trismus				
Date:06/16/ Age:	03ISR Number Gender:Male	: 4129550-2Report Type:Direct I/FU:I	Company Repor	rt #CTU 195877		
Outcome Dose	Duration	PT	Report Source	Product	Role Manufacturer	Route
Other	DULACION	Headache Pharmaceutical Product		Adderall 12.5 Mg Generic	PS	
1 TAB QAM		Complaint				

Date:06/19/ Age:41 YR	03ISR Number Gender:Male	r: 4188922-0Report Type:Periodi e I/FU:I	ic Company Repor	t #325146			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death		Completed Suicide	Literature Health	Klonopin (Clonazepam)	PS		ORAL
ORAL			Professional	Elavil (Amitriptyline Hydrochloride)	SS		ORAL
ORAL				Adderall (Amphetamine Aspartate/Amphetamin e			
ORAL				Sulfated/Dextroamphe	SS		ORAL
ORAL				Vioxx (Rofecoxib)	SS		ORAL
ORAL				Topamax(Topiramate)	SS		ORAL
ORAL				Geodon (Ziprasidone Hydrochloride)	SS		ORAL
				Remeron (Mirtazapine)	SS		ORAL
ORAL				Methadone (Methadone Hydrochloride)	SS		ORAL
ORAL				Neurontin	66		UKAL
ORAL				(Gabapentin)	SS		ORAL

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:06/20/03ISR Number: 4133721-9Report Type:Expedited (15-DaCompany Report #US0313100 Age:61 YR Gender:Female I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Duration Dose Other Mitral Valve Incompetence Health Adderall Xr PS 30 MG Pulmonary Hypertension Professional Adderal SS 25 MG Vasculitis "Supplements" No Ephedra С Date:06/20/03ISR Number: 4133727-XReport Type:Expedited (15-DaCompany Report #SUS1-2003-00069 Gender:Female I/FU:I Aqe: PTReport Source Role Manufacturer Outcome Product Route Duration Dose Cerebrovascular Accident Other Health Adderall Professional Family(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphet PS 20 MG Date:06/24/03ISR Number: 4134628-3Report Type:Direct Company Report #CTU 196502 Age: Gender:Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Adderall, Generic Other Drug Effect Decreased PS 10MG ONE PO Q Pharmaceutical Product AM, 0MG 1/2 Complaint PO Q PM

Date:06/24/03ISR Number: 4134746-XReport Type:Direct Company Report #CTU 196536 Age:10 YR Gender:Male I/FU:I

Outcome PT Report Source Product Role Manufacturer Dose Duration

Route

10MG PO QD	Eye Movement Disorder Grimacing Movement Disorder Tic		Adderall Xr 10mg Po Qd	PS	ORAL
Date:06/26/03ISR Numbe Age:6 YR Gender:Mal	er: 4135919-2Report Type:Direct .e I/FU:I	Company Repor	rt #CTU 196691		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration	Drug Ineffective Pharmaceutical Product Complaint		Adderall Generic	PS	
Date:07/01/03ISR Numbe Age:8 MON Gender:Mal	er: 4139941-1Report Type:Direct .e I/FU:I	Company Repor	rt #CTU 197043		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Life-Threatening 20MG ONCE	Anorexia		Adderal Xr	PS	
Hospitalization - DAILY	Convulsion				
Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Insomnia Psychotic Disorder Weight Decreased				

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:07/01/03ISR Number: 4140027-0Report Type:Direct Company Report #CTU 197019 Gender:Female Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Irritability Adderal 20 Mg PSONE DOSE TID Pharmaceutical Product Klonopin 0.5 Mg SS ONE DOSE QD Complaint TWO DOSES @HS Tofranil 25 Mg SS ONE DOSE TID Date:07/07/03ISR Number: 4144169-5Report Type:Expedited (15-DaCompany Report #SUS1-2003-00120 Age:11 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Other Convulsion Health Adderall Xr Refusal Of Treatment By Professional (Amphetamine Relative Aspartate) PS 30 MG, UNK, UNK Date:07/07/03ISR Number: 4144170-1Report Type:Expedited (15-DaCompany Report #SUS1-2003-00131 Age:56 YR Gender:Male I/FU:I  $\mathbf{PT}$ Role Manufacturer Outcome Report Source Product Route Duration Dose Other Arrhythmia Health Adderall Xr PS Supraventricular Professional Date:07/10/03ISR Number: 4144735-7Report Type:Direct Company Report #CTU 197639 Age:10 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Distractibility Adderall Generic PSORAL 30 MGM PO BID

		Disturbance In Attention Drug Effect Decreased Irritability Pharmaceutical Product Complaint					
	3ISR Number Gender:Male	: 4147742-3Report Type:Expedi I/FU:I	ted (15-DaCompany Rep	port #SUSI-2003-00139			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P	ion -	Chest Pain Dyspnoea Ventricular Extrasystoles	Consumer Other	Adderall Xr(Amphetamine Asparate, Amphetamine Sulfate,			
Date:07/14/0	2ISP Number	: 4148227-0Report Type:Expedi	ted (15-DaCompany Ret	Dextroamphetamine	PS		
Age:54 YR			ted (15 Dacompany ner	JUIC #5051 2005 0001,			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Supraventricular Tachycardia Syncope	Health Professional	Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
15 MG DAILY,				-	гъ		
				Aspirin "Bayer" (Acetylsalicylic			
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Freedom Of Information (FOI) Report

Acid) C Celebrex (Celecoxib) C Ultram (Tramadol Hydrochloride) C

Date:07/16/03ISR Number: 4151000-0Report Type:Expedited (15-DaCompany Report #SUS1-2003-00002 Age:42 YR Gender:Male I/FU:F

Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Death 15 MG, OTHE	Duration R,	Cardiac Arrest Ventricular Fibrillation	Health Professional	Adderall Xr(Dextroamphetamine Sulfate, Dextroamphetamine, Saccharate,	PS		ORAL
ORAL				Accuretic			
				(Hydrochlorothiazide , Quinapril			

Hydrochloride) C

Date:07/23/03ISR Number: 4154721-9Report Type:Expedited (15-DaCompany Report #SUSI-2003-00040 Age:23 YR Gender:Female I/FU:F

Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 10 MG,	Duration	Convulsion	Consumer Other	Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
2X/DAY:BID				Trileptal "Novartis" (Oxcarbazepine) Oral Contraceptive Nos (Oral Contraceptive Nos)	C C		

Date:07/31/03ISR Number: 4161898-8Report Type:Expedited (15-DaCompany Report #SUSI-2003-00171 Age:21 YR Gender:Female I/FU:I

Outcome Dose Dur	PT	Report Source	Product	Role	Manufacturer	Route
Other Other	Aphasia Convulsion Migraine	Consumer Other	Adderal(Dextroamphet amine Sulfate, Dextroamphetamine Saccharate, Amphetamine Sulfate, Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Zyrtec (Cetirizine Hydrochloride)	PS SS C		

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:07/31/03ISR Number: 4184906-7Report Type:Periodic Company Report #NSADSS2002039532 Gender:Male Aqe:9 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Extrapyramidal Disorder Health Risperdal Initial or Prolonged Professional (Risperidone) Tablets ΡS ORAL Company 3 MG, 2 IN 1 Representative DAY, ORAL Risperdal (Risperidone) SS ORAL 2 MG, 2 IN 1 DAY, ORAL Adderal Xr (Obetrol) Tablets ORAL SS 1 IN 1 DAY, ORAL Depakote (Valproate Semisodium) С Date:08/01/03ISR Number: 4163447-7Report Type:Expedited (15-DaCompany Report #US0229001 Age:12 YR Gender:Male I/FU:F Role Manufacturer Outcome PTReport Source Product Route Dose Duration Death Circulatory Collapse Health Adderall Xr PS 10 MG Sudden Cardiac Death Professional Company Representative Date:08/04/03ISR Number: 4160767-7Report Type:Direct Company Report #CTU 199143 Age: Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Abnormal Behaviour Lithobid 900-900 PS Anger Risperdal SS Drug Ineffective Adderall SS

		Dysthymic Disorder Emotional Disorder Negativism Thinking Abnormal		Depakote 1000 Strattera 80	SS SS		
Date:08/04/( Age:	03ISR Number: Gender:Male	: 4161008-7Report Type:Direct I/FU:I	Company Repor	rt #CTU 199129			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose 40		Flat Affect		Adderall-Xr	PS		
Date:08/04/( Age:	03ISR Number: Gender:Male	: 4161010-5Report Type:Direct I/FU:I	Company Repor	rt #CTU 199130			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose		Stereotypic Movement Disorder		Risperdal Adderall Xr 30	PS SS		
Date:08/04/( Age:	03ISR Number: Gender:	: 4161406-1Report Type:Direct I/FU:I	Company Repor	:t #USP 50427			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Medication Error		Adderall	PS	Richwood Pharmaceutical Co	
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Freedom Of Information (FOI) Report

Date:08/06/03ISR Number: 4166345-8Report Type:Expedited (15-DaCompany Report #SUSI-2003-00069 Gender:Female I/FU:F Age:

boe Duration Cerebrovascular Accident Professional Adderall (Amphetamine Apagratate, Amphetamine Sulfate, Destroamphetamine PS Date:08/06/03ISR Number: 4166350-IReport Type:Expedited (15-DaCompany Report 4SUSI-2003-00010 L/FU:F Dutcome Duration Duration Duration Duration SEE INAGE Date:08/11/03ISR Number: 4167877-9Report Type:Periodle Company Report 4SUSI-2003-00072 Mate:08/11/03ISR Number: 4167877-9Report Type:Periodle I/FU:T Dutcome PT Report Source Company Report 4SUSI-2003-00072 Report Source Product Report Source Product Report Source PS ORAL Risperdal (Risperda							
htter     Carebrovascular Accident     Health Professional     Addrall (Amphetamine Amphrtane, Amphrtane, Dextroamphetamine Sulfate, Dextroamphetamine Sulfate, Dextroamphetamine Sulfate, Dextroamphetamine     PS       vate:08/06/03ISR Number:     4166350-IReport Type:Expedited (15-DaCompany Report #SUSI-2003-00010 I/FUTF     PT     Report Source     Product     Role     Manufacturer     Route       vate:08/06/03ISR Number:     0 MG     DT     Report Source     Product     Role     Manufacturer     Route       vate:08/07/03IGR Duration     Abnormal Behaviour Perling Abnormal Behaviour Deschormel Desprint Disorder     Consumer Other     Addrall (Amphetamine Ampertane, Amphrtane,	Outcome Dose Duration		Report Source	Product	Role	Manufacturer	Route
20 MG Date:09/06/03ISE Number: 4166350-1Report Type:Expedited (15-DaCompany Report #SUSI-2003-00010 Jgg:9 YR Gender:Male I/FU:F Dutcome Duration Jospitalization - Ahormal Behaviour Consumer Adderall Precling Abnormal Behaviour Product Role Manufacturer Route Destroamphetamine Sulfate, Dextroamphetamine FS ORAL REE INAGE Adderall (Amphetamine Sulfate, Dextroamphetamine Sulfate, Amphetamine Sulfate, Dextroamphetamine Sulfate, Amphetamine Sulfate, IDEXTORMPHETINE SULFACE, Amphetamine SULFACE, A	Other			(Amphetamine Aspartate, Amphetamine Sulfate,			
Age:9 YR       Gender:Male       I/FU:F         Ducome Dospitalization - Duration Ospitalization - Initial or Prolonged       PT       Report Source       Product       Role Manufacturer       Route         SEE IMAGE       Abnormal Behaviour Peeling Abnormal Psychotic Disorder       Consumer Other       Adderall (Amphetamine Aspartate, Amphetamine Sapartate, Amphetamine Sapartate, Amphetamine Sulfate, Dextroamphetamine SSE       SS       ORAL         00 MG,       -	20 MG			Dextroamphetamine	PS		
bose Duration lospitalization - Initial or Prolonged Abormal Behaviour SEE IMAGE SEE			edited (15-DaCompany Re	eport #SUSI-2003-00010			
Iospitalization - Initial or Prolonged     Abnormal Behaviour Feeling Abnormal Psychotic Disorder     Consumer Other     Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Aspartate, Amphetamine Aspartate, Amphetamine SSE     ORAL       SEE IMAGE     Image: Ima	Outcome Dose Duration		Report Source	Product	Role	Manufacturer	Route
Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine SS ORAL 10 MG, 1XDAY:QD, DRAL Adderall (Amphetamine Sulfate, Dextroamphetamine SS ORAL Risperdal (Risperidone) C Company Report #SUSI-2003-00072 Age:19 YR Gender:Male I/FU:I Company Report #SUSI-2003-00072 PT Report Source Product Role Manufacturer Route	Hospitalization - Initial or Prolonged	Feeling Abnormal		(Amphetamine Aspartate, Amphetamine Sulfate,	20		07.14
Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine SS ORAL 10 MG, LXDAY:QD, DRAL Risperdal (Risperidone) c Date:08/11/03ISR Number: 4167877-9Report Type:Periodic Company Report #SUSI-2003-00072 Age:19 YR Gender:Male I/FU:I Dutcome PT Report Source Product Role Manufacturer Route Dose Duration	SEE IMAGE			Dextroamphetamine	PS		ORAL
LO MG, LXDAY:QD, ORAL Date:08/11/03ISR Number: 4167877-9Report Type:Periodic Age:19 YR Gender:Male I/FU:I Dutcome PT Report Source Product Role Manufacturer Route Dose Duration				(Amphetamine Aspartate, Amphetamine Sulfate,	66		OPAL
DRAL Risperdal (Risperidone) C Date:08/11/03ISR Number: 4167877-9Report Type:Periodic Company Report #SUSI-2003-00072 Age:19 YR Gender:Male I/FU:I Dutcome PT Report Source Product Role Manufacturer Route Dose Duration	10 MG,			DEVILOAIIIDHECAIIITHE	20		
Risperdal (Risperidone) C Date:08/11/03ISR Number: 4167877-9Report Type:Periodic Company Report #SUSI-2003-00072 Age:19 YR Gender:Male I/FU:I Dutcome PT Report Source Product Role Manufacturer Route Dose Duration	1XDAY:QD,						
(Risperidone) C Date:08/11/03ISR Number: 4167877-9Report Type:Periodic Company Report #SUSI-2003-00072 Age:19 YR Gender:Male I/FU:I Dutcome PT Report Source Product Role Manufacturer Route Dose Duration	ORAL						
Age:19 YR Gender:Male I/FU:I Outcome PT Report Source Product Role Manufacturer Route Dose Duration					С		
Dose Duration			iodic Company Re	eport #SUSI-2003-00072			
	Outcome		Report Source	Product	Role	Manufacturer	Route
	Dose Duration Hospitalization -		Other	Adderall Xr			

Hospitalization Initial or Prolonged Adderall Xr (Amphetamine

10 MG			Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
			Effexor (Venlafaxine Hydrochloride)	С		
Date:08/11/03ISR Numk Age: Gender:Ma	per: 4167879-2Report Type:Per ale I/FU:F	iodic Company Re	eport #US0211202			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - 40 MG	Insomnia	Consumer	Adderall Xr	PS		
Initial or Prolonged BID/7-15 DAYS	Paraesthesia					
	Psychotic Disorder Thinking Abnormal		Depakote And Clonazepam	С		
Date:08/18/03ISR Numk Age: Gender:Ma	per: 4172296-5Report Type:Exp ale I/FU:I	edited (15-DaCompany Re	eport #SUSI-2003-00131			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening	Atrial Fibrillation	Health Professional	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,			
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Freedom Of Information (FOI) Report

Dextroamphetamine PS

Date:08/26/03ISR Numb Age: Gender:Fe	per: 4174857-6Report Type:Direc emale I/FU:I	ct Company Re	eport #CTU 200704			
Outcome Dose Duratior	PT	Report Source	Product	Role	Manufacturer	Route
Other 10MG Q PO Q	Drug Effect Decreased		Adderall, Generic	PS		ORAL
AM; 10MG 1/2	Pharmaceutical Product					
PO QPM	Complaint					
Date:08/26/03ISR Numk Age:17 YR Gender:Ma	per: 4179651-8Report Type:Expectate I/FU:I	lited (15-DaCompany Re	eport #SUS1-2003-00221			
Outcome Dose Duratior	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Arteriospasm Coronary Myocardial Infarction	Health Professional	Adderall (Amphetamine Aspartate), Amphetamine Sulfate,			
10 MG,			Dextroamphetamine	PS		
2X/DAY: BID,			Advil (Ibuprofen)	С		
Date:08/29/03ISR Numk Age:9 YR Gender:Ma	per: 4179745-7Report Type:Expectale I/FU:I	lited (15-DaCompany Re	eport #SUS1-2003-00247			
Outcome Dose Duratior	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Idiopathic Thrombocytopenic Purpura	Health Professional	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,	Da		
10-30 MG			Dextroamphetamine	PS		

EVERY MORNING

Date:09/02/03 Age:38 YR G			: 4178681-XReport Type:Direct I/FU:I	Co	ompany Report	z #CTU 201044			
Outcome Dose	Durati	on	PT	Report Sou	urce	Product	Role	Manufacturer	Route
Life-Threaten	ing		Agitation			Adderall Xr			
Hospitalizati	on –		Anorexia			Extended-Release			
Initial or Pro 2 X/ DAY,	olonge	d	Anxiety			Capsules 30 Mg	PS		
Disability MORNING & 1			Asthma						
			Cardiac Failure						
PM	7	DAY	Congestive			Adderall Tablets 30			
			Congestive Cardiomyopathy			Mg	SS		
2X /DAY,									
MODITING AND 1			Dyspnoea						
MORNING AND 1			Fightion Exaction						
PM	5	YR	Ejection Fraction						
	-		Decreased Fatigue Insomnia Irritability Loss Of Consciousness Overdose Palpitations Respiratory Disorder Syncope			Effexor	С		

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:09/02/03ISR Number: 4178814-5Report Type:Direct Company Report #CTU 201130 Gender:Male Age:17 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Life-Threatening Agitation Adderall 10mg PS5 MG TWICE Hospitalization -Depression DAILY Initial or Prolonged Insomnia Suicidal Ideation Required Weight Decreased Intervention to Prevent Permanent Impairment/Damage Date:09/05/03ISR Number: 4180205-8Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0410183A Aqe:39 YR Gender:Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Glaxosmithkline Anxiety Requip PS ORAL 50MG See Chest Pain 1 YR dosage text Disorientation Neurontin SS UNKNOWN Effexor Pyrexia SS UNKNOWN Tremor Serzone SS UNKNOWN Flexeril SS UNKNOWN Adderall SS UNKNOWN Date:09/08/03ISR Number: 4183297-5Report Type:Direct Company Report #CTU 201393 Aqe:8 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Life-Threatening Anorexia Adderal Xr PS

Hospitalization - Weight Gain Poor

20 MG DAILY

Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage Date:09/10/03ISR Number: 4188536-2Report Type:Expedited (15-DaCompany Report #SUS1-2003-00252 Gender:Male Age:12 YR I/FU:I Role Manufacturer Outcome  $\mathbf{PT}$ Report Source Product Route Dose Duration Other Convulsion Other Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine ΡS 10 MG, 1X/DAY; QD Clonidine С Hydroxyzine С

Date:09/17/03ISR Number: 4192853-XReport Type:Expedited (15-DaCompany Report #SUS1 - 2003-00260 Age:7 YR Gender:Female I/FU:I

Outcome PT Other Abdominal Pain Upper Anorexia Haematochezia Insomnia Medication Error

Freedom Of Information (FOI) Report

		Weight Decreased					
Dose	Duration		Report Source	Product	Role	Manufacturer	Route
	Duración		Consumer Other	Adderall Xr	PS		
	3ISR Number Gender:Male	: 4202892-8Report Type:Expedit I/FU:I	ed (15-DaCompany Report	t #SUS1-2003-00289			
Outcome	Dunnation	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat Initial or P		Idiopathic Thrombocytopenic Purpura	Health Professional Other	Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
60 MG,							
1X/DAY:QD							
150,				Effexor-Xr(Venlafaxi ne Hydrochloride)	SS		
1X/DAY:QD							
15046.04 (224				Wellbutrin - Slow Release(Bupropion Hydrochloride)	SS		
150MG 2X/DAY							
	3ISR Number Gender:Fema	: 4204129-2Report Type:Expedit le I/FU:I	ed (15-DaCompany Report	t #HQWYE835223SEP03			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Drug Exposure During Pregnancy Intra-Uterine Death	Health Professional	Effexor Xr (Venlafaxine Hydrochloride, Capsule)	PS		ORAL
ORAL				Adderall (Amphetamine Aspartate/Amphetamin	10		

e Sulfate/Dexamfetamin SS

Date:10/06/03ISR Number: 4205656-4Report Type:Expedited (15-DaCompany Report #SUS1-2003-00343 Age:22 YR Gender: I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Complications Of Maternal Exposure To Therapeutic Drugs Intra-Uterine Death Pregnancy	Other	Adderall(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Effexor(Venlafaxine Hydrochloride)	PS SS		

Date:10/09/03ISR Number Age:6 YR Gender:Male	: 4208847-1Report Type:Direct I/FU:I	Company Report #CTU 203357
Outcome Other	PT Abnormal Behaviour Crying Emotional Disorder Intentional Self-Injury	

Freedom Of Information (FOI) Report

	Screaming					
	Sulcidal Ideation	Report Source	Product	Role	Manufacturer	Route
Duration			Adreall Xr 10mg	חפ	Chiro	ORAL
AL			SHILE	FO	SHILE	UKAL
03ISR Number Gender:Male		ced (15-DaCompany Repor	rt #SUS1-2003-00346			
	PT	Report Source	Product	Role	Manufacturer	Route
Duration	Abdominal Pain Upper Anorexia Drug Ineffective Dysphemia	Other	Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate, Devtroamphetamine	20		
			Dextroampnetamine	PS		ļ
	Logorrhoea					
	Medication Error Mood Swings Nervousness Overdose Rash					
		Company Repor	rt #CTU 203915			
	PT	Report Source	Product	Role	Manufacturer	Route
Duration	Drug Ineffective		Adderal 10mg Generic	PS		ORAL
03ISR Number Gender:Male		ted (15-DaCompany Repor	rt #USA-2003-0009933			
	PT	Report Source	Product	Role	Manufacturer	Route
Duration	Accidental Overdose	Health	Oxycontin Tablets			
	AL 03ISR Number: Gender:Male Duration 03ISR Number: Gender:Femal Duration	Suicidal Ideation Duration AL 03ISR Number: 4211864-9Report Type:Expedit Gender:Male I/FU:I PT Duration Abdominal Pain Upper Anorexia Drug Ineffective Dysphemia Headache Logorrhoea Medication Error Mood Swings Nervousness Overdose Rash 03ISR Number: 4210572-8Report Type:Direct Gender:Female I/FU:I PT Duration Drug Ineffective 03ISR Number: 4213775-1Report Type:Expedit Gender:Male I/FU:I PT Duration	Suicidal Ideation Duration AL D3ISR Number: 4211864-9Report Type:Expedited (15-DaCompany Repor Gender:Male I/FU:I PT Report Source Duration Abdominal Pain Upper Other Anorexia Drug Ineffective Dysphemia Headache Logorrhoea Medication Error Mood Swings Nervousness Overdose Rash D3ISR Number: 4210572-8Report Type:Direct Company Repor Gender:Female I/FU:I PT Report Source Duration Drug Ineffective D3ISR Number: 4213775-1Report Type:Expedited (15-DaCompany Repor Gender:Male I/FU:I PT Report Source Drug Ineffective PT Report Source Drug Ineffective Data I/FU:I PT Report Source Drug Ineffective Duration PT Report Source	Suicidal Ideation Duration Duration Duration Adreal1 Xr 10mg Shire AL  OSISR Number: 4211864-9Report Type:Expedited (15-DaCompany Report #SUS1-2003-00346 I/FU:I PT Report Source Product Anorexia Drug Ineffective Drug Ineffective Drug Ineffective Company Report #CTU 203915 Cender:Femate I/FU:I PT Report Source Product Company Report #CTU 203915 Cender:Femate I/FU:I PT Report Source Product Adderal 10mg Generic PT Duration PT Report Source Product PT PT Report Source Product PT PT Report Source Product PT	Suicidal Ideation Duration Duration Report Source Product Role Adreall Xr 10mg Shire PS AL P31SR Number: 4211864-9Report Type:Expedited (15-DaCompany Report #SUS1-2003-00346 I/FU'I PT Report Source Product Role Addemail Pain Upper Anorexia Drug Ineffective Dysphemia Headache Logorrhoea Medication Error Mood Swings Nervousness Overdose Rash D3ISR Number: 4210572-8Report Type:Direct Company Report #CTU 203915 Gender:Femile I/FU'I PT Report Source Product Role Addemail 10mg Generic PS Daration PT Report Source Product Role Addemail 10mg Generic PS Daration PT Report Source Product Role Role Role Role Role Role Role Role	Suicidal Ideation     Report Source     Product     Role     Manufacturer       Duration     AdrealI Xr 10mg Shire     FS     Shire       AL     211864-9Roport Type:Expedit (15-DaCompany Report #SUSI-2003-00346) (FUF):I     FS     Role     Manufacturer       Duration     PT     Report Source     Product     Role     Manufacturer       Duration     PT     Report Source     Product     Role     Manufacturer       Duration     AdderalI Anorexia Programeia     Other     AdderalI AdderalI Dextroamphetamine Appritatio, Ampletamine Sulfate, Dextroamphetamine Sulfate, Dextroamphetamine Sulfate, Dextroamphetamine     PS     FS       DiSER Number:     4210572-8Report Type:Direct     Company Report #CTU 203915     FS     Manufacturer       Diser Vandese Gender:Female     I/FU'I     Report Source     Product     Role     Manufacturer       Duration     PT     Report Source     Product     Role     Manufacturer </td

Other		Brain Oedema Coma	Professional Other	(Oxycodone Hydrochloride)Cr		
		Drug Screen Positive	other	Tablet	PS	
		Drug Toxicity		Hydrocodone		
		Excoriation		Bitartrate (Similar		
		Intentional Misuse		To Ind		
		Myocardial Fibrosis		59,175)(Hydrocodone	~~	
		Pulmonary Congestion		Bitartrate,	SS	
		Pulmonary Oedema Skin Laceration		Gamma		
				(Hydroxybutyrate)	SS SS	
		Ventricular Hypertrophy		Fentanyl(Fentanyl) Adderall (Amfetamine	22	
				Adderall (Amretamine Aspartate,		
				Amfetamine Sulfate,		
				Dexamfetamine		
				Saccharat	SS	
Date:10/20/0 Age:	03ISR Number Gender:Male	: 4214792-8Report Type:Expedi I/FU:F	ited (15-DaCompany Repor	t #SUS1-2003-00131		
Outcome		PT	Report Source	Product	Role	Manufacturer
Dose	Duration					
Life-Threate	ening	Atrial Fibrillation	Health	Adderall Xr		
			Professional	(Amphetamine		

Aspartate,

Route

Freedom Of Information (FOI) Report

Amphetamine Sulfate, Dextroamphetamine PS

Date:10/23/ Age:11 YR	03ISR Number Gender:Male	: 4215828-OReport Type:Direct	Company Repo	rt #CTU 204492			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Abnormal Behaviour Aggression		Adderall Xr 10mg Brookshires Bros Pharmacy	PS	Brookshires Bros	ORAL
1 CAPSUL ON	ICE					Pharmacy	ORAL
A DAY ORAL							
Date:10/24/ Age:19 YR	03ISR Number Gender:Fema	c: 4220030-2Report Type:Expedi- ale I/FU:I	ted (15-DaCompany Repo	rt #SUS1-2003-00399			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death		Convulsion Medication Error Myocardial Infarction Self-Medication	Other	Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
2-5 PILLS				-			
Date:10/24/ Age:38 YR	03ISR Number Gender:Male	: 4220033-8Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	rt #SUS1-2003-00374			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitaliza Initial or	ation -	Anorexia Anxiety Asthma Congestive Cardiomyopathy Ejection Fraction	Other	Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
SEE IMAGE		Decreased Feeling Jittery Hypertension		Adderall Xr(Amphetamine Aspartate,			

	Palpitations		Amphetamine Sulfate,			
I	Syncope		Dextroamphetamine	SS		
30 MG,						
1X/DAY: QD						
I			Effexor (Venlafaxine			
			Hydrochloride)	С		
			Lasix (Furosemide)	С		
Date:10/29/03ISR Numbe Age:6 YR Gender:Fem	er: 4223559-6Report Type:Exped: male I/FU:I	ited (15-DaCompany Re	eport #SUSI-2003-00395			
Outcome	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Accidental Exposure	Health	Adderall			
Initial or Prolonged	Psychomotor Hyperactivity	Professional	(Amphetamine			
			Aspartate,			
			Amphetamine Sulfate, Dextroamphetamine	PS		ORAL

5X15 MG

CAPSUES, ORAL

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:10/29/03ISR Number: 4223562-6Report Type:Expedited (15-DaCompany Report #SUSI-2003-00396 Gender:Male Age:12 YR I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Death Myocardial Infarction Health Adderall Tachycardia Professional (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine PS 15 MG, 2X/DAY: BID, Date:11/04/03ISR Number: 4227434-2Report Type:Expedited (15-DaCompany Report #US-03-034 Age:12 YR Gender:Male I/FU:F Outcome Role Manufacturer PTReport Source Product Route Dose Duration Life-Threatening Grand Mal Convulsion Health Adderall-Xr (Mixed Professional Amphetamine Salts) PS ORAL 20 MG Paxil С Risperdal С Date:11/07/03ISR Number: 4229881-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0388561A Gender:Female Age:42 YR I/FU:F Outcome PTReport Source Product Role Manufacturer Route Dose Duration Life-Threatening Chest Pain Health Wellbutrin PS Glaxosmithkline ORAL 150MG Twice Hospitalization -Professional Hypertension per day Initial or Prolonged Adderall SS UNKNOWN 20MG Unknown WΚ

Other

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Aphasia Drug Ineffective Unevaluable Event	Health Professional	Adderall Xr (Amphetamineaspartat e, Amphetamine Sulfate,			
15 MG				Dextroamphetamine	PS		
Date:11/07/ Age:5 YR	03ISR Number Gender:Male	: 4231438-3Report Type:Exp I/FU:I	pedited (15-DaCompany Re	eport #SUS1-2003-00309			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Aggression	Other	Adderall			
		Emotional Disorder Fear Medication Error		Xr(Amphetamine Aspartate, Amphetamine Sulfate,	PS		
30 MG,		Emotional Disorder Fear		Xr(Amphetamine Aspartate,	PS		
30 MG, 1x/day: Qd	26 DAY	Emotional Disorder Fear Medication Error Suicidal Ideation		Xr(Amphetamine Aspartate, Amphetamine Sulfate,	PS		

		FDA - Adverse Event Reporting System (AERS)							
			Freedom	Of Information (FOI) Re	eport				
Date:11/13/ Age:	03ISR Number Gender:Male	: 4235176-2Report Type:Direct I/FU:I	Company Repo	rt #CTU 206040					
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route		
Other	Duración	Urticaria		Generic For Adderal 20 Mg	PS		ORAL		
20 MG O.D.									
P.O.									
Date:11/14/ Age:8 YR	03ISR Number Gender:Male	: 4236439-7Report Type:Direct I/FU:I	Company Repo	ort #CTU 206147					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route		
0086	Duración	Medication Tampering		Adderall Xr 20 Mg Capsules -Made By					
HALF CAPSUI	ιE			Shire	PS	Shire	ORAL		
BY MOUTH IN	1								
AM									
Date:11/17/ Age:11 YR	03ISR Number Gender:Male	: 4237243-6Report Type:Expedit I/FU:I	ed (15-DaCompany Repo	rt #SUSI-2003-00426					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route		
Other		Agitation Delusional Disorder, Persecutory Type Drug Interaction Hallucination, Visual	Health Professional	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS				
20 MG,				-					
1X/DAY, QD		Heart Rate Increased							
		Social Avoidant Behaviour		Lexapro (Escitalopram)	SS				
10 MG, ,									
a /									

1X/DAY, QD

Date:11/18/ Age:	03ISR Number: Gender:	: 4237630-6Report Type:Direct I/FU:I		Company Repor	t #CTU 206401			
Outcome Dose	Duration	PT Medication Error	Report	Source	Product Adderall Tablets Mfd By Shire	Role PS	Manufacturer Shire	Route
Date:11/19/ Age:	03ISR Number: Gender:Male	: 4238258-4Report Type:Direct I/FU:I		Company Repor	t #CTU 206437			
Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose 5 MG FOUR (		Abnormal Behaviour			Adderall	PS		
AM THREE Q		Aggression Pharmaceutical Product Complaint						
	03ISR Number: Gender:Male	: 4242829-9Report Type:Periodi I/FU:I	C	Company Repor	t #SUSI-2003-00374			
Outcome Hospitaliza Initial or	tion - Prolonged	PT Anorexia Anxiety Asthma Congestive Cardiomyopathy Feeling Jittery						
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Freedom Of Information (FOI) Report

		Hypertension Palpitations Syncope	Report	z Source	Product	Role	Manufacturer	Route
Dose UNKNOWN	Duration 30 MG,		Other		Adderall(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Saccharate,	PS		
2X/DAY; BID;								
UNK					Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	SS		
UNKNOWN	30 MG,				Deneroupne			I
1X/DAY, QD;								
UNK (SEE								
IMAGE)					Effexor (Venlafaxine Hydrochloride) Lasix (Furosemide)	C C		
	3ISR Number Gender:Male	r: 4242832-9Report Type:Periodi e I/FU:I	ic	Company Repor	t #SUSI-2003-00010			
Outcome	Deschion	PT	Report	: Source	Product	Role	Manufacturer	Route
Dose Hospitalizat: Initial or Pr		Psychotic Disorder	Other		Adderall(Amphetamine Aspartate, Amphetamine Sulfate, Amphetamine			
5 MG,					Dextroamphetamine	PS		ORAL
1X/DAY;QD,								

ORAL

			Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	SS	ORAL
10 MG,			Dextroampheramine		UIAL
1X/DAY;QD,					
ORAL (SEE					
IMAGE)			Risperdal (Risperidone)	с	
Age:38 YR Gender:Male			port #SUSI-2003-00176		Devel
Age:38 YR Gender:Male Outcome Dose Duration Hospitalization - Initial or Prolonged	PT Congestive Cardiomyopathy	dic Company Rep Report Source Health Professional	port #SUSI-2003-00176 Product Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	Role Manufacturer PS	Route
Age:38 YR Gender:Male Outcome Dose Duration Hospitalization - Initial or Prolonged UNKNOWN 30 MG,	PT Congestive Cardiomyopathy	Report Source Health	Product Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,		Route
Age:38 YR Gender:Male Outcome Dose Duration Hospitalization - Initial or Prolonged	PT Congestive Cardiomyopathy	Report Source Health	Product Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,		Route

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:11/21/03ISR Number: 4242836-6Report Type:Periodic Company Report #SUSI-2003-00218 Gender:Female Age: I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Other Gastrointestinal Injury Consumer Adderall Xr(Amphetamine Rash Papular Somnolence Aspartate, Weight Decreased Amphetamine Sulfate, Dextroamphetamine PS UNKNOWN 30 MG, UNK, UNK Date:11/21/03ISR Number: 4242838-XReport Type:Periodic Company Report #SUSI-2003-00225 Age:19 YR Gender:Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Other Psychotic Disorder Health Adderall Xr Professional Weight Decreased (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine PS20 MG PER UNKNOWN DAY, UNK (SEE IMAGE) Claritin (Loratadine) С Plaquenile С Vitamins С Date:11/24/03ISR Number: 4241769-9Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20031103820 Age:16 YR Gender:Male I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Death Brain Death Health Concerta Cardiac Arrest Professional (Methylphenidate Cerebral Haemorrhage Hydrochloride) Drug Abuser Sustained Release

		Drug Ineffective		Tablets	PS	ORAL
36 MG, 3 IN 1		Drug Interaction				
DAY, ORAL		Diug Interaction				
				Adderall (Obetrol)	SS	
				Cocaine (Cocaine)	SS	
	SR Number: nder:Male	: 4244638-3Report Type:Exp I/FU:I	edited (15-DaCompany Re	eport #SUSI-2003-00456		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Du Other	uration	Convulsion	Other	Adderall Xr		
00112_		Electroencephalogram	•	(Amphetamine		
		Abnormal		Aspartate,		
		Hypoaesthesia		Amphetamine Sulfate, Dextromethamine	PS	ORAL
20 MG,						01u
1X/DAY:QD,						
ORAL; 15 MG,						
1X/DAY:QD,						
ORAL	274 DAY					

Freedom Of Information (FOI) Report

Date:12/03/ Age:	03ISR Number Gender:Male	: 4246276-5Report Type:Direct I/FU:I		Company Repor	t #CTU 207399			
Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose	Duration		-1					
Congenital 150 MG PO Q	Anomaly	Congenital Foot			Zoloft	PS		ORAL
_		Malformation						
DAILY								
		Congenital			Depakote	SS		
		Musculoskeletal Anomaly			Adderal	SS		
		Congenital Nose			Xanax	SS		ORAL
3.5 MG PO 1	ID	2						
		Malformation						
		Facial Dysmorphism						
		Hydrocele						
		Low Set Ears						
		Maternal Drugs Affecting						
		Foetus						
		Microqnathia						
		Multiple Congenital						
		Abnormalities						
		Penis Disorder						
Date:12/09/ Age:10 YR	03ISR Number Gender:Male	: 4248962-XReport Type:Direct I/FU:I		Company Repor	t #CTU 207808			
Outcome		РТ	Report	Source	Product	Role	Manufacturer	Route
Dose	Duration							
Other		Abdominal Pain Upper			Adderall 10 Mg			
		Feeling Abnormal			Generic	PS		
10 MG Q AM	5	-						
		Vomiting						
MG Q NOON		-						
		: 4250316-7Report Type:Direct		Company Repor	t #CTU 207898			
Age:23 YR	Gender:Fema	le I/FU:I						
		2	<b>.</b> .	2				<b>.</b> .
Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose	Duration							
Other		Cerebrovascular Accident			Adderall 20 Mg	PS		ORAL
20 MG 3 TIM	ES							

Required ORAL		Complications Of Maternal					
Intervention to Prevent Permanent Impairment/Damage		Exposure To Therapeutic Drugs Foetal Cerebrovascular Disorder Induced Labour Maternal Drugs Affecting Foetus Pre-Eclampsia					
	)3ISR Number Gender:Fema	: 4252026-9Report Type:Direct le I/FU:I	Company Re	port #CTU 208103			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other BID	Duration	Drug Effect Decreased Pharmaceutical Product		Generic Adderall 20 Mg	PS		
		Complaint					
	)3ISR Number Gender:Male	: 4252311-0Report Type:Direct I/FU:I	Company Re	port #CTU 208176			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duración	Drug Effect Decreased Pharmaceutical Product Complaint		Shire Us Imc -Adderall	PS	Shire Us Imc	
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FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:12/16/03ISR Number: 4252316-XReport Type:Direct Company Report #CTU 208172 Gender: Age: I/FU:I Role Manufacturer Outcome PTReport Source Product Route Duration Dose Distractibility Adderall PSORAL 10 MG PO Q Disturbance In Attention DAY Dizziness Adderall Xr SS Lethargy Pharmaceutical Product Complaint Date:12/16/03ISR Number: 4253890-XReport Type:Direct Company Report #CTU 208287 Aqe:37 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Adderall Other Drug Ineffective PS ORAL 20 PO TID Nausea [MAINTAINANCE Pharmaceutical Product ] Valuim Complaint SS 10 BID 15 HS С Vomiting Lorcet Date:12/17/03ISR Number: 4254534-3Report Type:Expedited (15-DaCompany Report #SUS1-2003-00493 Age:19 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Duration Dose Death Medication Error Health Adderall Professional (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine PS INTRAVENOUS INTRAVENOUS

Date:12/18/0	3ISR Number:	: 4254917-1Report Type:Direct		Company Report	t #CTU 208417			
Age:51 YR (		I/FU:I						I
Outcome	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other		Drug Ineffective Pharmaceutical Product Complaint			Adderall Tablets 20 Mg, 100 Ct Bt; Mfd By Shire	PS	Shire	ORAL
1 TAB BY		Comptaine			By DILLC	FD	51111 6	010111
MOUTH 3 X A								
DAY/ MAYBE								I
SEVERAL YEARS	3				Adderall Tablets 20 Mg, 100 Ct Bt; Mfd By Shire	SS	Shire	
1 TAB BY					By DILLC	00	SIITE	ľ
моитн 3 х а								
DAY/ MAYBE								ľ
SEVERAL YEARS	3							
Date:12/18/03 Age:45 YR (		: 4264971-9Report Type:Periodi I/FU:I	ic	Company Repor	t #HQWYE948110MAR03			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other ABOVE 300 MG		Hypertension	Health		Effexor Xr	PS		ORAL
			Profess	sional				
DAILY, ORAL			Company	y entative	Adderall (Amfetamine Aspartate/Amfetamine	9.9		
20 MG EACH			1/02+02		Abpat cace, mit comment			
AM, 10 MG								
EACH PM								
22-Aug-2005 Page: 128	10:34 AM							

Freedom Of Information (FOI) Report

Norvasc (Amlodipine Besilate) C

Date:12/18/03ISR Number: 4274169-6Report Type:Periodic Company Report #HQWYE667725FEB03 Age:20 YR Gender:Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Duration Dose Effexor Xr Other Anxiety Consumer (Venlafaxine Confusional State Depression Hydrochloride, Dizziness Capsule, Extended Drug Interaction Release) PS ORAL 37.5 MG 1X Drug Withdrawal Syndrome PER 1 DAY, Feeling Abnormal ORAL; 75 MG Muscle Tightness 1X PER 1 DAY, Pain ORAL Paraesthesia Adderall (Amfetamine Suicidal Ideation Aspartate/Amfetamine Tension Sulfate/Dexamfetamin е Saccharate/Dexamfeta SS 20 MG 2X PER

1 DAY; "2-3

MONTHS

Outcome

Dose

Ambien (Zolpidem Tartrate) C Ultracet (Tramadol Hydrochloride/Parace tamol) C

Date:12/19/03ISR Number: 4255453-9Report Type:Direct Age:15 YR Gender:Female I/FU:I

PT

Duration

Company Report #CTU 208458E

Report Source

Product

Hospitalization - ONCE DAILY	Bruxism		Strattera Eli Lilly	PS	Eli Lilly	ORAL
Initial or Prolonged ORAL	Diplopia					
Required	Dyskinesia		Addrall Xr 20 Mg			
Intervention to ONCE DAILY	Dystonia		Shire Richwood	SS	Shire Richwood	ORAL
Prevent Permanent ORAL	Medication Error					
Impairment/Damage	Mydriasis Myoclonus					
Data:12/10/02TCD Number	: 4256548-6Report Type:Exped	lited (15 Declements D				
Age:6 YR Gender:Male Outcome Dose Duration		Report Source	eport #SUSI-2003-00507 Product	Role	Manufacturer	Route

Freedom Of Information (FOI) Report

Date:12/19/03ISR Number: 4256552-8Report Type:Expedited (15-DaCompany Report #SUSI-2003-00501 Age:16 YR Gender:Male I/FU:I

4							
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Death	Duración	Brain Death Cardiac Arrest Cerebral Haemorrhage Drug Ineffective	Other	Adderall (Amphetamine Aspartate, Amphetamine Sulfate,			
				Dextroamphetamine Concerta (Methylphenidate	PS		
36 MG 3 IN 1				(Methylphenidate Hydrochloride)	SS		ORAL
DAY, ORAL							
				Cocaine (Cocaine)	SS		
Age:9 YR Outcome	Gender:Male	: 4256799-OReport Type:Expedia I/FU:F PT	Report Source	Product	Role	Manufacturer	Route
Outcome Dose Hospitalizat Initial or P		PT Idiopathic Thrombocytopenic Purpura	Report Source Health Professional	Product Adderall Xr (Amphetamine Aspartate,	Role	Manufacturer	Route
10.20 MC				Amphetamine Sulfate, Dextroamphetamine	PS		
10-30 MG							
EVERY MORNIN	ŗ						
	3ISR Number Gender:Male	: 4258509-XReport Type:Expedit I/FU:F	ted (15-DaCompany Repor	ct #SUS1-2003-00396			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Daración	Circulatory Collapse Coronary Artery Disease Dizziness Myocardial Infarction	Health Professional	Adderall (Amphetamine Aspartate, Amphetamine Sulfate,			
15MG, 2X/DAY	:	Palpitations		Dextroamphetamine	PS		

## Tachycardia

BID

Date:12/23/03ISR Number: 4258513-1Report Type:Expedited (15-DaCompany Report #SUS1-2003-00510 Age:17 YR Gender:Male I/FU:I

Outcome	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Durat Death	ion Aspiration Brain Oedema Completed Suicide Multiple Drug Overdose Prescribed Overdose Pulmonary Congestion	Health Professional	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Seroquel (Quetiapine Fumarate) Lamotrigine (Lamotrigine) Effexor (Venlafaxine Hydrochloride) Carbamazepine (Carbamazepine) Sertraline (Sertraline)	PS SS SS SS SS		

				FDA – Adv	erse Event Reporting Syste	m (AER	S)	
				Freed	om Of Information (FOI) Re	port		
	03ISR Number Gender:Male	: 4263026-7Report ' I/FU:I	Type:Periodic	Company R	eport #HQWYE948110MAR03			
Outcome Dose	Duration	РТ	Rep	ort Source	Product	Role	Manufacturer	Route
Other	Duración	Hypertension	Com	lth fessional pany resentative	Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended			
"ABOVE 300 N	MG				Release	PS		ORAL
DAILY", ORAI	L				Adderall (Amfetamine Aspartate / Amfetamine Sulfate/Dexamfetamin	SS		
20 MG EACH					e	55		
AM, 10 MG								
EACH PM					Norvasc (Amlodipine Besilate)	С		
	03ISR Number Gender:Femal	: 4263154-6Report ' le I/FU:I	Type:Periodic	Company R	eport #HQWYE667725FEB03			
Outcome		PT	Rep	ort Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Anxiety Confusional State Depression Dizziness		sumer	Effexor Xr (Venlafaxine Hydrochloride, Capsule, Extended			
37.5 MG 1X		Drug Interaction			Release)	PS		ORAL
PER 1 DAY,		Drug Withdrawal S	yndrome					
ORAL; 75 MG		Feeling Abnormal Muscle Tightness						
1X PER 1 DAY	Υ,	Pain						
ORAL		- 411						

		Paraesthesia Suicidal Idea Tension	tion			Adderall (Amfetamineaspartate / Amfetamine			
						Sulfate/Dexamfetamin e	SS		
20 MG 2X PE	IR					C	55		
1 DAY	3 MON								
						Ambien (Zolpidem Tartrate) Ultracet (Tramadol Hydrochloride/Parace	С		
						tamol	С		
Date:01/04/ Age:	04ISR Number Gender:Male		ort Type:Direct		Company Repo	ort #CTU 209284			
Outcome		PT		Report	Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Drug Ineffect	ive			Adderall Xr 20 Mg Shire	PS	Shire	ORAL
2 CAPSUL ON	ICE					5	10	5	01112
DAILY ORAL									
	04ISR Number Gender:Male		ort Type:Direct		Company Repo	ort #CTU 209444			
Outcome Life-Threat Hospitaliza									
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FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Initial or Prolonged Disability Role Manufacturer PTReport Source Product Route Duration Dose Psychotic Disorder Adderall PS ONE A DAY Date:01/06/04ISR Number: 4266307-6Report Type:Expedited (15-DaCompany Report #SUS1-2003-00531 Gender:Male Age:13 YR I/FU:I Route Outcome PTReport Source Product Role Manufacturer Dose Duration Other Dystonia Health Adderall Xr PSSEE IMAGE Professional Date:01/12/04ISR Number: 4269803-0Report Type:Expedited (15-DaCompany Report #US0301702 Gender:Female Age:19 YR I/FU:F Role Manufacturer Outcome PTReport Source Product Route Duration Dose Life-Threatening Apallic Syndrome Health Adderall ΡS SEE NARRATIVE Arrhythmia Professional Cardiac Arrest Cardiac Failure Congestive Cardiomyopathy Circulatory Collapse Drug Screen Positive Ejection Fraction Decreased Nodal Rhythm Self-Medication Ventricular Hypertrophy

Ventricular Tachycardia

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Anorexia	Other	Adderall Xr			
		Depression		(Amphetamine			,
		Hypersomnia		Aspartate,			
l		Insomnia		Amphetamine Sulfate,			r
		Persecutory Delusion		Dextroamphetamine	PS		r
30 MG,		-		-			,
		Treatment Noncompliance					,
2X/DAY:BID	183 DAY						,
1		Weight Decreased		Synthroid			,
1				(Levothyroxine			,
1				Sodium)	С		,
1				Mirtazapine	~		ŗ
1				(Mirtazapine)	С		,
1				(mir cazapine)	C		ŗ
1							,
l							,
Data:01/20//	NATER Numbe	er: 4276651-4Report Type:Expe	edited (15-DaCompany R	eport #SUST_2004_00002			,
	Gender:Male		arcea (15 Dacompany ne	POLC #2021 2001 00002			,
Age II II	Genuer - mare						,
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	1 1	Report Source	1104400	1010	Manaraccarcr	100000
Other	Duración	Anger	Other	Adderall(Dextroamphe			
Other		Condition Aggravated	Other	tamine Sulfate,			
4		CONDICION Aggravated		tamine Suitate,			,

Dextroamphetamine

PS

Saccharate, Amphetamine

Adderall Xr

Impulsive Behaviour

Theft

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		FDA - Advers	se Event Reporting Syste	em (AERS)	
		Freedom	Of Information (FOI) Re	eport	
15 MG,			(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	SS	
2X/DAY:BID,UN					
К			Adderall (Amphetamine Aspartate, Amphetamine Sulfate,		
15 MG,			Dextroamphetamine	SS	
2X/DAY:BID,					
UNK			Neurontin (Gabapentin) Motrin (Ibuprofen) Asthma Medication Nos	с с с	
Date:01/21/04ISR Numbe Age: Gender:Fem	er: 4277578-4Report Type:Direct male I/FU:I	Company Repc	ort #CTU 210601		
Outcome Dose Duration Other 10G PO TID	PT Headache Pharmaceutical Product Complaint	Report Source	Product Adderall (Generic) 10g Tid	Role Manufacture PS	er Route ORAL
Date:01/21/04ISR Numbe Age:16 YR Gender:Fem	er: 4278296-9Report Type:Direct male I/FU:I	Company Repo	ort #CTU 210579		
Outcome Dose Duration Other 10 MG TID	PT Drug Effect Decreased Pharmaceutical Product Complaint	Report Source	Product Adderall (Generic)	Role Manufacture PS	er Route

Date:01/22/	04ISR Number:	4278714-6Report	Type:Expedited	(15-DaCompany	Report	#SUSI-2004-00014	
Age:17 YR	Gender:Male	I/FU:I					

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Durución	Abdominal Pain Bone Marrow Depression Platelet Count Decreased Splenomegaly	Health Professional	Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		ORAL
20 MG, 1 X				2 offor campile camile	10		01112
/DAY, QD,							
ORAL							
	4ISR Number Gender:Fema	: 4279183-2Report Type:Direct le I/FU:I	Company Repor	t #CTU 210758			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Headache Pharmaceutical Product		Adderall (Generic) 10 Mg Tid	PS		ORAL
10G PO TID		Complaint					

Freedom Of Information (FOI) Report

Date:01/28/04ISR Number: 4281979-8Report Type:Expedited (15-DaCompany Report #SUS1-2003-00551 Age:16 YR Gender:Male I/FU:I

1								
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
	Duración	Back Pain Clonus Hyperreflexia Nerve Conduction Studies Abnormal	Other		Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
50 MG		Nerve Injury			Vitamins	С		
	4ISR Number Gender:Male	: 4283634-7Report Type:Direct I/FU:I		Company Report	t #CTU 211090			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Hospitalizat: 20 MG PO QD		Exhibitionism			Adderall Xr 10 Mg	PS		ORAL
Initial or P:	rolonged	Hallucination, Visual			Tylenol Mom Maalox	C C C		
	4ISR Number Gender:Fema Duration	: 4282838-7Report Type:Periodi le I/FU:I PT	ic Report		t #US-BRISTOL-MYERS SQI Product		COMPANY-12286415 Manufacturer	Route
		Drug Withdrawal Syndrome			Serzone Tabs 100 Mg	PS	Bristol-Myers Squibb Company	ORAL
100 mg daily							_	
in the								
evening,meds								
not taken fo:								

			Flexeril Adderall	SS SS	
"Adderall XR"					I
PARENTERAL			Vitamin B12	C	ľ
					ľ
Date:02/03/04ISR Number: Age:17 YR Gender:	: 4285065-2Report Type:Direct I/FU:I	Company Repo:	ort #CTU 211384		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
	Abdominal Pain		Adderall Tab	PS	ľ
	Apathy Disturbance In Attention				
Date:02/03/04ISR Number: Age:11 YR Gender:Femal	: 4285719-8Report Type:Direct le I/FU:I	Company Repo	ort #CTU 211471		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Other	Abnormal Behaviour Educational Problem		Adderall 20 Mg-Generic	PS	ORAL
20 MG 2 EACH	Pharmaceutical Product		-		ļ
AM ONE A NOON					I
ONE AT 4:00PM	Complaint				
ORALLY					

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:02/06/04ISR Number: 4290171-2Report Type:Expedited (15-DaCompany Report #SUSI-2004-00039 Aqe:31 YR Gender:Male I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Hospitalization -Epididymitis Other Adderall Paranoia (Amphetamine Initial or Prolonged Psychotic Disorder Asparate, Amphetamine Sulfate, Dextroamphetamine PS 210 MG PER DAY Date:02/10/04ISR Number: 4293854-3Report Type:Expedited (15-DaCompany Report #SUSI-2004-00052 I/FU:I Gender:Male Age: Role Manufacturer Outcome PTReport Source Product Route Dose Duration Hospitalization -Suicide Attempt Other Adderall Initial or Prolonged (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine PSDate:02/10/04ISR Number: 4293864-6Report Type:Expedited (15-DaCompany Report #SUSI-2004-00051 Age:8 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Chest Pain Other Adderall Xr Initial or Prolonged Dyspnoea (Amphetamine Fatique Aspartate, Headache Amphetamine Sulfate, Sedation Dextroamphetamine PS Date:02/11/04ISR Number: 4296560-4Report Type:Periodic Company Report #SUS1-2003-00383 Age:11 YR Gender:Male I/FU:I PTReport Source Product Role Manufacturer Route Outcome Dose Duration

Other	Psychotic Disorder Tic	Other	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,			
20 MG,			Dextroamphetamine	PS		
1X/DAY:QD 365 DAY	¥		Adderall (Amphetamine Aspartate,			
5 MG 365 DAX	Y		Amphetamine Sulfate, Dextroamphetamine	SS		
			Albuterol (Salbutamol)	С		
Date:02/11/04ISR Number Age:6 YR Gender:Male	r: 4296562-8Report Type:Period e I/FU:I	lic Company Rep	oort #SUS1-2003-00459			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Hypertension	Other	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
5 MG,						

Freedom Of Information (FOI) Report

1X/DAY:QD

		: 4296564-1Report Type:Periodi	.c Company Repor	t #SUS1-2003-00546			
Age:18 YR	Gender:Fema	ale I/FU:I					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or F	tion -	Psychotic Disorder	Health Professional	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
10 MG				Dener camping the	-~		
1X/DAY:QD							
				Strattera /Usa/(Tomoxetine Hydrochloride)	С		
Date:02/12/0 Age:	04ISR Number Gender:Male	: 4294175-5Report Type:Direct I/FU:I	Company Repor	rt #CTU 212184			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duración	Medication Error		Adderall 20 Mg Shire Richwood	PS	Shire Richwood	ORAL
20 MG -10/10	C					<b>5</b>	••
TID ORAL							
	04ISR Number Gender:Male	r: 4297175-4Report Type:Expedit e I/FU:I	.ed (15-DaCompany Repor	∙t #SUS1-2004-00071			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Abnormal Behaviour Drug Abuser Hallucination Legal Problem	Health Professional	Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate,			
30 MG DAILY,		Psychotic Disorder		Dextroamphetamine	PS		ORAL

		Thinking Abnormal						
ORAL					Valium			
					/Net/(Diazepam) Unspecified Pain	SS		
					Medication() Marijuana(Marijuana)	SS		!
					Marıjuana(Marıjuana)	SS		
Date:02/16/ Age:6 YR	04ISR Number Gender:Male	: 4294957-XReport Type:Periodic I/FU:F	С	Company Report	t #US-GLAXOSMITHKLINE-A	A04002	:39A	
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
DOSE	Duración	Abnormal Behaviour			Lamictal	PS	Glaxosmithkline	ORAL
50MG Per da	ay 1 YR				Adderall Xr	SS		ORAL
MON								-
Date:02/18/ Age:	04ISR Number Gender:	: 4299670-0Report Type:Direct I/FU:I		Company Report	t #CTU 212531			
Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose	Duration	Drug Ineffective Pharmaceutical Product Complaint			Adderall	PS		

			FDA - Adve	erse Event Reporting Syste	em (AEI	RS)	
			Freedo	om Of Information (FOI) Re	eport		
Date:02/18, Age:	/04ISR Number Gender:	: 4299674-8Report Type:Dire I/FU:I	ct Company Re	eport #CTU 212538			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Drug Ineffective Pharmaceutical Product Complaint		Adderall	PS		
Date:02/18, Age:	/04ISR Number Gender:	: 4299675-XReport Type:Dire I/FU:I	ct Company Re	eport #CTU 212540			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Drug Effect Decreased Pharmaceutical Product Complaint		Adderall	PS		
Date:02/23, Age:8 YR	/04ISR Number Gender:Male	: 4303466-0Report Type:Expe I/FU:I	dited (15-DaCompany Re	eport #SUSI-2004-00083			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Complex Partial Seizures Drug Ineffective	Other	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,			
30 MG, 1 X				Dextroamphetamine	PS		
/DAY.QD				Zoloft (Sertraline Hydrochloride)	С		
Date:02/24, Age:	/04ISR Number Gender:	: 4304262-0Report Type:Expe I/FU:F	dited (15-DaCompany Re	eport #US012622			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Convulsion	Health Professional	Provigil Adderall	PS SS		

Date:03/04/0 Age:8 YR	)4ISR Number: Gender:Male	4311746-8Report Type:Direct I/FU:I		Company Repor	t #CTU 213853			
Outcome Dose Other	Duration	PT Attention Deficit/Hyperactivity Disorder Insomnia Pharmaceutical Product Complaint	Report	Source	Product Adderall Daw 5 Mg	Role PS	Manufacturer	Route
	)4ISR Number: Gender:Femal	4375989-XReport Type:Direct e I/FU:I		Company Repor	t #CTU 220396			
Outcome Dose Death	Duration	PT Completed Suicide Injury Asphyxiation	Report	Source	Product Adderall Xr 20 Mg Q Day	Role PS	Manufacturer	Route ORAL
20 MG Q DAY ORAL 10 MG Q DAY					Lexapro 10 Mg	SS		ORAL
ORAL								
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					Event Reporting Syste		S)	
						2010		
Date:03/10/( Age:	)4ISR Number: Gender:Male	4315325-8Report Type:Direct I/FU:I		Company Report	t #CTU 214246			
Outcome Dose	Duration	PT	Report	Source	Product Adderall Generic And	Role	Manufacturer	Route
Other 5 MG		Drug Ineffective Pharmaceutical Product			Brand Name	PS		
INCREASED TO		Complaint						
20					Concerta	SS		
18 INCREASIN	1G					55		
TO 54					Strattera	SS		
Age:41 YR Outcome	Gender:Femal	4341276-9Report Type:Periodi e I/FU:I PT	c Report		F #SUSI-2004-00018 Product	Role	Manufacturer	Route
Dose Hospitalizat Initial or H		Cardiomyopathy	Consume	er	Adderall (Amphetamine Aspartate, Amphetamine Sulfate,	PS		
SEE IMAGE					Dextroamphetamine Clonazepam (Clonazepam) Clomipramine	С		
					(Clomipramine) Topiramate (Toopiramate)	C C		
	)4ISR Number: Gender:Male	4318701-2Report Type:Direct I/FU:I		Company Report	z #CTU 214425			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
20 MG -PO -		Disturbance In Attention			Adderall Generic	PS		ORAL

Drug Effect Decreased

Pharmaceutical Product Complaint

Date:03/17/04ISR Number: 4319926-2Report Type:Expedited (15-DaCompany Report #SUSI-2004-00118 Age:13 YR Gender:Female I/FU:I

Outcome PTHospitalization -Aggression Initial or Prolonged Agitation Blood Pressure Increased Body Temperature Decreased Cardiac Disorder Cardiac Murmur Dyspnoea Electrocardiogram Qt Prolonged Headache Intentional Misuse Myocardial Infarction Nausea Overdose Pulmonary Oedema Respiratory Rate Increased

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TAKE 2

5AM

Freedom Of Information (FOI) Report

Dose	Duration	Sinus Tachycardia Ventricular Extrasystoles Vomiting	Report Source	Product	Role	Manufacturer	Route
DOBE	Duración	White Blood Cell Count Increased	Literature Health Professional	Adderall(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine			
				Saccharate,) Adderall (Dextroamphetamine Sulfate)	PS		
				(Dextroamphetamine Saccharate,	SS		
Date:03/19/( Age:	)4ISR Number Gender:Fema	: 4320565-8Report Type:Direct le I/FU:I	Company Repor	rt #CTU 214836			
Outcome	Dunchion	PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Hallucination, Visual Pharmaceutical Product Complaint		Adderall Xr Ritalin La 20 Mg	PS SS		
	)4ISR Number Gender:Male	: 4320971-1Report Type:Direct I/FU:I	Company Repor	t #CTU 214912			
Outcome	Dunchion	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Feeling Abnormal Oral Pain		Adderall Xr 30 Mg Shire Pharmacuetical	PS	Shire Pharmacuetical	ORAL
ONE CAP DAII	ĽΥ	Stevens-Johnson Syndrome		Shire marmacacercar	10		OIUIL
ORAL		Stevens-Johnson Syndrome					
Date:03/29/( Age:11 YR	)4ISR Number Gender:Male	: 4330711-8Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #SUSI-2004-00178			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Agitation	Other	Adderall Xr			

10 MG,	Anorexia Dyspnoea Medication Tampering Pallor		(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS	
1X/DAY:QD					
			Guanfacine		
4			(Guanfacine)	C	
			Multivitamin	C	
Date:04/02/04ISR Number Age:33 YR Gender:Fema	: 4333176-5Report Type:Direct le I/FU:I	Company Repo:	rt #CTU 215819		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Outcome		Report Source	Product St. Johns Wart	Role Manufacturer PS	Route ORAL
Outcome Dose Duration Life-Threatening	PT	Report Source			
Outcome Dose Duration Life-Threatening STANDARD DOSE Hospitalization -	PT Back Pain	Report Source			

Freedom Of Information (FOI) Report Date:04/05/04ISR Number: 4334306-1Report Type:Expedited (15-DaCompany Report #SUS1-2004-00117 Gender:Male Age:49 YR I/FU:I Route Outcome PΤ Report Source Product Role Manufacturer Dose Duration Other Skin Exfoliation Consumer Adderall Stevens-Johnson Syndrome Xr(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine PS 30 MG, 1X/DAY:QD Date:04/09/04ISR Number: 4338712-0Report Type:Direct Company Report #CTU 217003 Age:35 YR Gender:Female I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Other Abdominal Pain Twice-A- Day 12 Hour Back Pain Nasal Spray (Mfgd Diarrhoea By Propharma) PS Propharma NASAL NASAL SPRAY Gastrointestinal Disorder Prevacid SS Levsin SS Birth Control Ortho Tricycline SS Adderall SS Date:04/09/04ISR Number: 4338975-1Report Type:Expedited (15-DaCompany Report #SUSI-2004-00184 Age:15 YR Gender:Male I/FU:I ΡТ Role Manufacturer Outcome Report Source Product Route Duration Dose Hospitalization -Acute Coronary Syndrome Health Adderall Xr Initial or Prolonged Arteriospasm Coronary Professional (Amphetamine Blood Creatine Aspartate, Phosphokinase Increased Amphetamine Sulfate, Dizziness Dextroamphetamine PS 40 MG PER DAY Drug Screen Positive Electrocardiogram St-T

Segment Elevation

FDA - Adverse Event Reporting System (AERS)

Date:04/15/04 Age:19 YR (		: 4339754-1Report Type:Direct I/FU:I		Company Report	с #CTU 216692			
Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose Life-Threate 30 MG DAILY	Duration ening	Haemorrhage			Adderall Xr 30 Mg	PS		I
		Hypersensitivity Intentional Self-Injury Obsessive Thoughts Paranoia Weight Decreased			Citalopram	С		
	)4ISR Number: Gender:Male	: 4340057-XReport Type:Direct I/FU:I		Company Report	t #CTU 216729			
Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose Other 12.5 2 BID PO		Abnormal Behaviour			Adderall	PS	Barr Laboratory	ORAL
12.0 2 222 -		Pharmaceutical Product Complaint						

		FDA – Adve	rse Event Reporting Syste	em (AER	RS)	
			m Of Information (FOI) Re			
Date:04/19/04ISR Numb Age:9 YR Gender:Ma	er: 4342497-1Report Type:Direc le I/FU:I	ct Company Re	port #CTU 216901			
Outcome Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other 5 MG QAM	Urticaria		Adderall 5 Mg	PS		
Date:04/20/04ISR Numb Age: Gender:Ma	er: 4342325-4Report Type:Direc le I/FU:I	ct Company Re	port #CTU 216927			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Disability Other Required 60 MG. DAY	Abnormal Behaviour Agitation Apathy		Adderall 10 Mg Shire Pharmaceuticals	PS	Shire Pharmaceuticals	ORAL
Intervention to ORAL	Bruxism					
Prevent Permanent Impairment/Damage	Drug Withdrawal Syndrome Euphoric Mood Impaired Work Ability Mental Disorder Neurotoxicity Paranoia Psychotic Disorder Suicidal Ideation Thinking Abnormal Weight Decreased		Luvox	С		
Date:04/23/04ISR Numb Age: Gender:Ma	er: 4346243-7Report Type:Direc le I/FU:I	ct Company Re	port #CTU 217299			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged Disability Required Intervention to Prevent Permanent Impairment/Damage	Cardiac Failure Congestive Cardiomegaly Chest Pain Drug Abuser Gallop Rhythm Present Haemoptysis Myocarditis		Adderall Amphetamine-Mixed-Sa lts -Shire Pharm Fluoxetine Furosemide	PS C C	Shire Pharm	

		Nasopharyngitis Pallor Peripheral Coldness Tachypnoea Wheezing						
	04ISR Number: Gender:Male	4348971-6Report Type:Direct I/FU:I		Company Repor	rt #CTU 217488			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Dose		Decreased Appetite Drug Effect Decreased Tic			Ritalin Concerta Adderal	PS SS SS		
	)4ISR Number: Gender:Male	4350394-OReport Type:Direct I/FU:I		Company Repor	rt #CTU 217521			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other		Abnormal Behaviour Pharmaceutical Product			Adderall Generic Barr Laboratory	DC	Down Johanshawa	0.0.2.1
12.5 TWO BII		Complaint			4/27/04 1200	PS	Barr Laboratory	ORAL
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Freedom Of Information (FOI) Report

Route

ORAL

Route

PO

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Age:15 MON Gender:Female
                              I/FU:I
                        PT
                                                        Report Source
                                                                                                     Role Manufacturer
Outcome
                                                                               Product
             Duration
Dose
Hospitalization -
                                                        Health
                                                                               Adderall Xl
                        Accidental Exposure
                                                        Professional
Initial or Prolonged
                        Agitation
                                                                               (Amphetamine
                        Anorexia
                                                                               Aspartate,
                        Blood Creatine
                                                                               Amphetamine Sulfate,
                        Phosphokinase Increased
                                                                               Dextroamphetamine
                                                                                                     PS
5 TO 10 30MG
                        Discomfort
(150-300MG),
                        Fatique
ORAL
                        Heart Rate Increased
Date:04/30/04ISR Number: 4353634-7Report Type:Expedited (15-DaCompany Report #SUS1-2004-00240
Age:8 YR
            Gender:Female
                              I/FU:I
                        PT
                                                                                                     Role Manufacturer
Outcome
                                                        Report Source
                                                                               Product
             Duration
Dose
Other
                        Anorexia
                                                        Consumer
                                                                               Adderall Xl
                        Balance Disorder
                                                        Other
                                                                               (Amphetamine
                        Convulsion
                                                                               Aspartate,
                                                                               Amphetamine Sulfate,
                        Dizziness
                        Medication Error
                                                                               Dextroamphetamine
                                                                                                     PS
20 MG,
                        Nausea
1X/DAY:QD
Date:04/30/04ISR Number: 4353642-6Report Type:Expedited (15-DaCompany Report #SUSI-2004-00210
Age:29 YR
            Gender:Male
                              I/FU:I
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Date:04/30/04ISR Number: 4353632-3Report Type:Expedited (15-DaCompany Report #SUS1-2004-00212

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalization -		Abnormal Behaviour	Health	Adderall Xr			
Initial or Prolonged		Agitation	Professional	(Amphetamine			
Other		Drug Dependence		Aspartate,			

	Facial Bones Fracture		Amphentamine		
	Fall Medication Error Psychotic Disorder Tooth Injury		Sulfate,	PS	
Age:11 YR Gender:1					
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duratio					
Other	Agitation	Consumer	Adderall Xr		
4	Anorexia	Other	(Amphetamine		
			(Implie comfile		
	Dyspnoea		Aspartate,		
	Dyspnoea Medication Tampering				
			Aspartate,	PS	
10 MG,	Medication Tampering		Aspartate, Amphetamine Sulfate,	PS	
10 MG,	Medication Tampering		Aspartate, Amphetamine Sulfate,	PS	
10 MG, 1XDAY:QD	Medication Tampering Pallor		Aspartate, Amphetamine Sulfate,	PS	

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:05/11/04ISR Number: 4361125-2Report Type:Periodic Company Report #SUS1-2004-00057 Age:21 YR Gender:Male I/FU:I Route Outcome PTReport Source Product Role Manufacturer Dose Duration Hospitalization -Depression Other Adderall Xr Initial or Prolonged Drug Abuser (Dextroamphetamine Panic Attack Sulfate, Psychotic Disorder Dextroamphetamine Sacharate, PS Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine SS Inhaler Nos С Date:05/11/04ISR Number: 4361126-4Report Type:Periodic Company Report #SUS1-2004-00078 Aqe:11 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Adderall Xr Other Heart Rate Increased (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine PS 30 MG, 1X/DAY: QD, Date:05/12/04ISR Number: 4357822-5Report Type:Expedited (15-DaCompany Report #SUSI-2004-00212 Age:15 MON Gender:Female I/FU:F Outcome PTReport Source Product Role Manufacturer Route Dose Duration Hospitalization -Abnormal Behaviour Health Adderall Initial or Prolonged Accidental Exposure Professional Xr(Amphetamine Agitation Sulfate, Anorexia Dextroamphetamine Blood Creatine Sacchrate, PS ORAL 5 TO 10 30MG

(150 200MC)		Phosphokinase Increased				
(150-300MG),		Drug Effect Decreased				
ORAL		Fatigue Heart Rate Increased Multiple Drug Overdose				
	4ISR Number Gender:Male	: 4360958-6Report Type:Expe I/FU:I	edited (15-DaCompany Re	eport #SUSI-2004-00225		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose Other 30 MG, 1	Duration	Abnormal Behaviour Anger Paranoia Psychotic Disorder	Health Professional	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS	
X/DAY, QD	3 DAY	- -		Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	99	ORAL
20 MG,				Dextroampnetamine	SS	ORAL
1X/DAY, QD,						
ORAL						
22-Aug-2005 Page: 143	10:34 AM					

Freedom Of Information (FOI) Report

			Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	SS		
25 MG,						
1X/DAY/QD 7 DA	Y					
Date:05/25/04ISR Numbe Age: Gender:Mal	r: 4369184-8Report Type:Exped: e I/FU:I	ited (15-DaCompany Re	eport #SUS1-2004-00289			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Other	Medication Tampering	Other	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,			
25 MG			Dextroamphetamine	PS		
Date:05/26/04ISR Numbe Age:18 YR Gender:Fem	r: 4372690-3Report Type:Exped: ale I/FU:I	ited (15-DaCompany Re	eport #SUSI-2004-00292			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Blood Potassium Decreased Grand Mal Convulsion Incontinence Neutrophil Percentage Increased	Health Professional	Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
UNKNOWN 20MG			Dextroampheramine	PD		
15MG NOON,						
UNK (SEE						
IMAGE) 30 DA	Y					

Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other	Duración	Grand Mal Convulsion	Other		Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
UNKNOWN	UNK, U	NK, UNK			Dextroamplietamille	ĽЪ		
	4ISR Number Gender:Fema	: 4367876-8Report Type:Direct le I/FU:I		Company Report	t #CTU 219786			
Outcome	Dumation	PT	Report	Source	Product	Role	Manufacturer	Route
Dose Death	Duration	Completed Suicide			Lexapro 10 Mg Forest Pharaceuticals	PS	Forest Pharaceuticals	ORAL
1/2 DOSE EA								01112
MORNIN ORAL					Adderalln Xr 30 Mg Shire Us Inc.	SS	Shire Us Inc.	ORAL
1 DOSE EA.					SHILE US THE.	66	Shire os file.	UKAL
MORNIN ORAL					Adderalln Xr 30 Mg	66	China IIa Ina	
					Shire Us Inc.	SS	Shire Us Inc.	

Freedom Of Information (FOI) Report

Date:06/08/04ISR Number: 4376654-5Report Type:Expedited (15-DaCompany Report #SUS1-2004-00318 Age:42 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Anxiety	Health	Adderall			
			Professional	Xr(Amphetamine			
				Aspartate,			
				Amphetamine Sulfate,			
				Dextroamphetamine	PS		
30 MG							

Date:06/10/04ISR Number: 4379548-4Report Type:Expedited (15-DaCompany Report #SUS1-2004-00330 Age:6 YR Gender:Female I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Acute Psychosis Agitation Chest Pain Convulsion Drug Screen Positive	Other	Adderall(Amphetamine Asparate, Amphetamine Sulfate, Dextroamphetamine Saccarate,	PS		
5 MG TITRATED						
TO 20 MG AM,	Drug Toxicity					
10 mg prn,	Dystonia					
io ng rid,	Eye Movement Disorder		Adderall	SS		
30 MG,	Hallucination, Visual					
1X/DAY, QD	harraothacton, vibaar					
	Initial Insomnia Irritability Movement Disorder Musculoskeletal Stiffness		Zantac (Ranitidine Hydrochloride) Floonase (Fluticasone	С		
	Pain In Extremity		Propionate)	С		
	Respiratory Arrest Screaming		Mirlax Montelukast Sodium	С		
	Tachycardia		(Montelukast Sodium) Zyrtec (Cetirizine	С		
			Hydrochloride)	С		
			Advair	С		

	lISR Number: Gender:	4379557-5Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #SUS1-2004-00331			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Myocardial Infarction	Health Professional	Adderall(Amphetamine , Asparate, Amphetamine Sulfate, Dextroamphetamine Saccarate,	PS		
20 MG,				Baccarace,	10		
3X/DAY:TID							
	lISR Number: Gender:Male	4385322-5Report Type:Direct I/FU:I	Company Repor	t #USP 56655			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Medication Error		Adderall 10 Mg	PS		
TABLET				Methylphenidate 10 Mg	SS		
TABLET					55		

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:06/17/04ISR Number: 4382904-1Report Type:Expedited (15-DaCompany Report #SUSI-2004-00282 Age:11 YR Gender:Male I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Dose Duration Other Aggression Other Adderall (Amphetamine Anger Aspartate, Educational Problem Amphetamine Sulfate, Obsessive Thoughts Dextroamphetamine Saccharate, PS 365 DAY Date:06/17/04ISR Number: 4382907-7Report Type:Expedited (15-DaCompany Report #SUSI-2004-00341 Age:12 YR Gender:Male I/FU:I PTReport Source Product Role Manufacturer Outcome Route Dose Duration Other Condition Aggravated Health Adderall Xr Convulsion Professional (Amphetamine Convulsive Threshold Aspartate, Lowered Amphetamine Sulfate, Dextroamphetamine PS 60 MG, 2X/DAY, BID Depakote (Valproate Semisodium) С Date:06/21/04ISR Number: 4382298-1Report Type:Direct Company Report #CTU 221111 Gender:Male I/FU:I Age: Outcome PTReport Source Product Role Manufacturer Route Dose Duration Abnormal Behaviour Generic Adderall ORAL Hospitalization -PS 15 MG BID PO Initial or Prolonged Drug Ineffective Pharmaceutical Product Complaint

Date:06/21/04ISR Number: 4396177-7Report Type:Periodic Age:19 YR Gender:Male I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death Other	Duración	Accidental Overdose Drug Abuser	Health Professional	Oxycontin Tablets (Oxycodone			
		Dysarthria	Other Hydroch	Hydrochloride)	PS		
	Multiple Drug Overdose		Hydrocodone				
		Psychomotor Hyperactivity		Bitartrate (Similar			
			( I	To Ind 59,175)			
				(Hydrocodone	<b></b>		
				Bitartrate) Adderall	SS		
				(Dexamfetamine			
				Sulfate, Amftamine			
				Sulfat)	SS		
				Prozac (Fluoxetine			
				Hydrochloride)	SS		
				Cocaine (Cocaine)	SS		I
				Trazodone			
1				(Trazodone)	SS		1
1				Nefazodone			1
1				(Nefazodone)	SS		1
1				Caffeine (Caffeine)	SS		
1				Nicotine (Nicotine) Oxymorphone	SS		
				(Oxymorphone)	SS		
				(OXYMOLDHOILE)	20		

Freedom Of Information (FOI) Report

Xanax (Alprazolam) SS

Date:06/23 Age:25 YR	/04ISR Number Gender:Male	: 4383882-1Report Type:Direct I/FU:I	Company Repor	t #CTU 221263			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other 10MG "0"		Drug Effect Decreased		Adderal Xr 10 Mg	PS		
5 MG "O"		Pharmaceutical Product		Adderal Xr 5 Mg	SS		
		Complaint					
Date:06/23 Age:10 YR	/04ISR Number Gender:Male	: 4386546-3Report Type:Expedit I/FU:I	ed (15-DaCompany Repor	t #SUSI-2004-00361			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Deafness Bilateral Glaucoma Retinal Haemorrhage	Health Professional	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,	DC		
25 MG,				Dextroamphetamine	PS		
1X/DAY,QD							
Date:06/25 Age:9 YR	/04ISR Number Gender:Male	: 4385339-0Report Type:Direct I/FU:I	Company Repor	t #USP 56658			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other TABLET		Medication Error		Dexedrine 5 Mg	PS	Skb	
TABLET				Adderal 5 Mg	SS	Shrine	

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other DAILY IN AM	Drug Ineffective		Adderall 30mg	PS		
Date:06/28/04ISR Numbe Age:45 YR Gender:Fer	er: 4390039-7Report Type:Exped male I/FU:I	dited (15-DaCompany Re	eport #SUS1-2004-00356			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged	Headache Hypertension Malignant Hypertension	Health Professional	Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
10 MG,						
1X/DAY:QD			Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	SS		
5 MG, 2X/DAY:			Dereroumpriceumrie	66		
BID 28 DA	ΥY					

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:06/29/04ISR Number: 4387121-7Report Type:Direct Company Report #CTU 221809 Gender:Female Age: I/FU:I Outcome PΤ Report Source Product Role Manufacturer Route Duration Dose Other Abdominal Pain Adderall Xr 20 Mg PS 1 DAILY Anorexia Cyanosis Lupus-Like Syndrome Skin Ulcer Date:07/02/04ISR Number: 4393926-9Report Type:Expedited (15-DaCompany Report #SUSI-2004-00361 Age:9 YR Gender:Male I/FU:F PTReport Source Product Role Manufacturer Outcome Route Duration Dose Disability Blindness Health Adderall Xr Deafness Bilateral Professional Other (Amphetamine Eye Haemorrhage Aspartate, Glaucoma Amphetamine Sulfate, Retinal Haemorrhage Dextroamphetamine PS 20 MG, 1X/DAY: QD Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine SS Date:07/07/04ISR Number: 4394303-7Report Type:Expedited (15-DaCompany Report #SUS1-2004-00387 Age:4 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Abnormal Behaviour Health Adderall Xr Insomnia Professional (Amphetamine Medication Error Aspartate, Mental Impairment Amphetamine Sulfate, Dextroamphetamine PSORAL 30 MG ONE

TIME,	ORAL
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ration Arteriospasm Corona Myocardial Infarcti		Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
		Dexcroamphecamine			
			гIJ		
	pe:Expedited (15-DaCompany	Report #SUS1-2004-00178			
PT	Report Source	Product	Role	Manufacturer	Route
ration					
Agitation	Other	Adderall Xr			
Anorexia		(Amphetamine			
		Aspartate,			
Dyspnoea					
Medication Error		Amphetamine Sulfate,			
	Э	Amphetamine Sulfate, Dextroamphetamine	PS		
Medication Error Medication Tamperin	Э	_	PS		
Dygnnoea					
Medication Error	Э	_	PS		
	der:Male I/FU:F PT ration Agitation	der:Male I/FU:F PT Report Source ration Agitation Other	PT Report Source Product ration Agitation Other Adderall Xr	der:Male I/FU:F PT Report Source Product Role ration Agitation Other Adderall Xr	der:Male I/FU:F PT Report Source Product Role Manufacturer ration Agitation Other Adderall Xr

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Freedom Of Information (FOI) Report

Guanfacine C Multiple Vitamins (Ascorbid Acid, Ergocalciferol, Folic Acid, Retinol, Tocopherol, Vitamin C

Date:07/20/0 Age:	)4ISR Number Gender:Male	r: 4402756-0Report Type:Dir E I/FU:I	ect Company Re	eport #CTU 223117			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Life-Threate 2X PER ORAL	Duration ening	Cardiac Monitoring		Adderall 10 Mg	PS		ORAL
Required MORNING ORAI	J	Heart Rate Increased		Adderall 30 Mg-Xr	SS		ORAL
Intervention Prevent Perr Impairment/I	nanent	Heart Rate Irregular Palpitations					
Date:07/21/( Age:8 YR	)4ISR Number Gender:Male	r: 4407153-XReport Type:Exp e I/FU:I	edited (15-DaCompany Re	eport #SUSI-2004-00404			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other	2 42 402 011	Drug Ineffective Medication Tampering	Other	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,	DC		
10 MG				Dextroamphetamine	PS		
Date:07/21/( Age:5 YR	)4ISR Number Gender:Male	: 4407161-9Report Type:Exp E I/FU:I	edited (15-DaCompany Re	eport #SUSI-2004-00409			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Chest Pain Heart Rate Increased Hyperhidrosis Pallor	Health Professional	Adderall (Dextroamphetamine Sulfate, Dextroamphetamine			

Saccharate,	PS
Saccial acce,	- 0

1/2 OF 5-MG

TABKET ONE

TIME

Strattera (Tomoxetine Hydrochloride) C

Date:07/27/04ISR Number: 4412869-5Report Type:Expedited (15-DaCompany Report #2004-BP-05595BP Age:8 YR Gender:Female I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged 0.2 MG (0.1	Electrocardiogram Abnormal	Health Professional	Catapres Tablets (Clonidine)	PS	ORAL
	Po2 Decreased				
MG, 1 TABLET	Psychiatric Symptom				
BID), PO	Skin Discolouration		Adderall Xr (Obetrol)	SS	
20 MG					

Freedom Of Information (FOI) Report

Date:08/02/04ISR Number: 4413136-6Report Type:Direct Age:16 YR Gender:Female I/FU:I Company Report #CTU 224034

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate Other 15 MG 1XDAII	ening	Abnormal Dreams Alopecia		Adderall Xr 15 Mg Shire	PS	Shire	ORAL
		Amnesia					
MOR ORAL		Anorexia		Zoloft 200 Mg Pfizer	SS	Pfizer	ORAL
200 MG 1X							
DATLY ODAL		Bacterial Infection					
DAILY ORAL		Balance Disorder Condition Aggravated Confusional State Depression Dizziness Drug Ineffective Drug Tolerance Eye Infection Fatigue Fungal Infection Genital Infection Bacterial Heart Rate Increased Heart Rate Increased Heart Rate Irregular Infection Insomnia Loss Of Consciousness Mania Medication Error Migraine Mood Altered Muscular Weakness Nausea Overdose Psychotic Disorder Rash Weight Decreased White Blood Cell Count Abnormal					

Date:08/02/04ISR Number: 4416711-8Report Type:Expedited (15-DaCompany Report #SUS1-2004-00425 Age:8 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Electrocardiogram	Other	Adderall Xr			
Initial or Prolonged	Abnormal		(Amphetamine			
Other	Oxygen Saturation		Aspartate,			
	Decreased	(Amphetamine Aspartate,	Amphetamine Sulfate,			
	Psychiatric Symptom		Dextroamphetamine,	PS		
20 MG						ļ
1	Skin Discolouration		Catapres (Clonidine0	SS		
0.1 MG,						
2X/DAY: BID						

Date:08/02/04ISR Number: 4416911-7Report Type:Expedited (15-DaCompany Report #SUS1-2004-00424 Age:22 YR Gender:Male I/FU:I Outcome PT Hospitalization - Abnormal Behaviour Initial or Prolonged Agitation Aspartate Aminotransferase Increased 22-Aug-2005 10:34 AM

Freedom Of Information (FOI) Report

Dose	Duration	Blood Bilirubin Increased Blood Creatine Phosphokinase Increased	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Chorea Drug Screen Positive Logorrhoea Nausea Tremor	Literature Health Professional	Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextramphetamine	PS		
45 MG,							
3X/DAY:TID	5 day			Escitalopram (Escitalopram)	С		
	)4ISR Number Gender:Male	: 4425488-1Report Type:Expedit	ced (15-DaCompany Repor	rt #SUS1-2004-00433			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Aggression Self Injurious Behaviour Suicide Attempt	Other	Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
5MG UP TO				Dexeroampreeamrie	10		
20MG ONCE							
DAILY							
				Tenex (Guanfacine Hydrochloride) Albuterol (Salbutamol)	C C		
	)4ISR Number Gender:Male	: 4445492-7Report Type:Period: I/FU:I	ic Company Repor	rt #SUS1-2004-00310			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duracion	Psychotic Disorder	Other	Adderall Xr (Amphetamine Aspartate,			

	Amphetamine Sulfate, Dextroamphetamine	PS
30 MG,		
1X/DAY:QD,		
	Adderall Xr(Dextroampehtamine Sulfate, Dextroamphetamine Saccharate,	SS
10 MG,		
2X/DAY:BID;		
10 MG,		
1X/DAY:QD,	Adderall (Ampheteramine Asparatate, Amphetamine Sulfate, Dextroamphetamine	SS
10 MG,		

1X/DAY:QD

				FDA – Adv	erse Event Reporting Syste	em (AEF	RS)	
				Freed	om Of Information (FOI) Re	eport		
Date:08/10/ Age:16 YR	/04ISR Number Gender:Male	: 4445493-9Report Typ I/FU:I	pe:Periodic	Company F	eport #SUS1-2004-00364			
Outcome Dose	Duration	PT	Rep	ort Source	Product	Role	Manufacturer	Route
Other	Daración	Psychotic Disorder	Oth	er	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine	Þđ		
INCREASED 7	ГО				Saccharate,	PS		
40MG IN A.M	4.,				Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	SS		
10 MG,					TT			
1X/DAY:QD Date:08/12/ Age:27 YR	/04ISR Number Gender:Fema		pe:Expedited (	15-DaCompany F	eport #SUS1-2004-00440			
Outcome		PT	Rep	ort Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Dizziness Hypoglycaemia	Hea Pro	lth fessional	Adderall (Amphetamine Aspartate, Amphetamine Sulfate,			
10 MG,					Dextroamphetamine	PS		ORAL
3X/DAY:TID,	,							
ORAL								
					Klonopin (Clonazepam) Tylenol Centrum (Vitamins Nos, Minerals Nos) Depo Provera (Medroxyprogesterone	C C C		
					Acetate)	С		

Date:08/18/04ISR Num Age: Gender:I	mber: 4431158-6Report Type:Expe Male I/FU:I	edited (15-DaCompany R	eport #SUSI-2004-00453			
Outcome Dose Duratio	PT	Report Source	Product	Role	Manufacturer	Route
Other	Blood Pressure Increased Myocardial Infarction Vascular Occlusion	Health Professional	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		ORAL
SEE IMAGE			2011020ump1100um110			01010
D 4 400 (10 (0470D N						
Age:28 YR Gender:I Outcome	PT	edited (15-DaCompany R Report Source	eport #SUS1-2004-00463 Product	Role	Manufacturer	Route
Age:28 YR Gender:1	Male I/FU:I PT Cardiomyopathy		Product Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,		Manufacturer	Route
Age:28 YR Gender:1 Outcome Dose Duratio Hospitalization -	Male I/FU:I PT ON Cardiomyopathy d Hypertension Myocardial Infarction	Report Source	Product Adderall Xr (Amphetamine Aspartate,	Role PS	Manufacturer	Route

Freedom Of Information (FOI) Report

Aspartate, Amphetamine Sulfate, Dextroamphetamine SS

SEE IMAGE 1830 DAY

Date:08/20/04ISR Number: 4432578-6Report Type:Expedited (15-DaCompany Report #SUSI-2004-00457 Age:12 YR Gender:Male I/FU:I

Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other	24240201	Tic	Consumer	Adderall Xr(Amphetamine Asparate, Amphetamine Sulfate, Dextroamphetamine	PS		ORAL
30 MG,				Dexcloamphecamine	Po		UKAL
1X/DAY,							
QD,ORAL				D Amphetamine Salt			
10 MG,				Combo	SS		ORAL
1X/DAY, QD,							
ORAL							
	4ISR Number Gender:Male	: 4433434-XReport Type:Expedite I/FU:I	ed (15-DaCompany Report	t #SUSI-2004-00484			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Other	Durución	Convulsion	Health Professional	Adderall(Amphetamine Aspartate,Amphetamin e Sulfate,Dextroamphet			
ORAL				amine Saccharate,	PS		ORAL

Outcome Dose	Duration	PT	Report S	Source	Product	Role	Manufacturer	Route
Life-Threater	ling	Suicide Attempt			Adderal 25 Mg	PS		
Date:08/30/04 Age:17 YR G		4437556-9Report Type:Direct Le I/FU:I		Company Report	: #CTU 225873			
Outcome Dose	Duration	PT	Report S	Source	Product	Role	Manufacturer	Route
Hospitalizati 5 MG DAILY		Amnesia			Adderall Xr 5 Mg	PS		ORAL
Initial or Pr ORAL	colonged	Delusion						
5 MG DAILY		Disorientation			Dexadrine 5 Mg	SS		ORAL
ORAL		Eating Disorder						
		Insomnia Mania						
		Memory Impairment Mental Disorder Psychomotor Hyperactivity Repetitive Speech Sleep Disorder Speech Disorder						

				erse Event Reporting Syst om Of Information (FOI) R		RS)	
	4ISR Number Gender:Male	: 4438715-1Report Type:Direct I/FU:I	t Company R	eport #CTU 225882			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate ONCE DAILY		Amnesia		Adderal Xr 25 Mg	PS		
Required Intervention Prevent Perm Impairment/D	anent	Cardiac Disorder Tachycardia Weight Decreased					
Date:09/01/0 Age:14 YR		: 4678686-6Report Type:Direct le I/FU:I	t Company R	eport #CTU 239868			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Required 30 MG BID	Duration	Drug Effect Decreased		Generic Adderall	PS		
Intervention Prevent Perm Impairment/D	anent	Therapeutic Response Unexpected With Drug Substitution					
	4ISR Number Gender:Fema	: 4444695-5Report Type:Exped: le I/FU:I	ited (15-DaCompany R	eport #SUS1-2004-00483			
Outcome	<b>D</b>	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Hypotrichosis Sleep Disorder Suicidal Ideation	Consumer	Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate,	DG		
20 MG,				Dextroamphetamine	PS		
1X/DAY:QD				Prozac (Fluoxetine Hydrochloride)	С		
				Buspar (Buspirone Hydrochloride)	С		

	4ISR Number Gender:Male	: 4445201-1Report Type:Ex I/FU:I	pedited (15-DaCompany Re	eport #SUS1-2004-00513			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Convulsion	Health Professional	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
20 MG,				-			
1X/DAY; QD							
	4ISR Number Gender:Fema	: 4445203-5Report Type:Ex le I/FU:I	pedited (15-DaCompany Re	eport #SUS1-2004-00500			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Asthma Cough Throat Irritation	Consumer	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,			
15 MG, 1X,				Dextroamphetamine	PS		

1X/DAY;QD

Freedom Of Information (FOI) Report

Date:09/03/04ISR Number: 4445205-9Report Type:Expedited (15-DaCompany Report #SUS1-2004-00497 Age:32 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration		-				
Hospitalizat Initial or P:	rolonged	Abnormal Behaviour Bipolar Disorder Delusion Depression Drug Dependence	Health Professional	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
30 MG,				-			
		Hallucination, Auditory					
1X/DAY;QD							
		Mania		Paxil (Paroxetine	00		
20 MG,		Paranoia		Hydrochloride)	SS		
20 MG,		Psychotic Disorder					
1X/DAY; QD							
-		Treatment Noncompliance					
Date:09/08/0 Age:55 YR (		: 4445550-7Report Type:Direct I/FU:I	Company Repor	t #CTU 226560			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Blood Pressure Diastolic Increased		Adderall 10 Mg Abrika	PS	Abrika	ORAL
2 EA							
		Drug Effect Decreased					
TWICE/DAY							
ORAL		Dysgeusia					
URAL		Impaired Work Ability Influenza Pharmaceutical Product Complaint Somnolence					
	4ISR Number: Gender:Femal	: 4451559-XReport Type:Expedit le I/FU:F	ed (15-DaCompany Repor	t #2004-BP-05595BP			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route

Hospitalization - Initial or Prolonged	Electrocardiogram Abnormal	Health Professional	Catapres Tablets (Clonidine)	PS	ORAL
0.2 MG (0.1			( ) = ) = )		01112
	Po2 Decreased				
MG,1 TABLET					
BID), PO					
			Adderall Xr		
NR (20 MG),			(Obetrol)	SS	
NR (20 MG),					
NR					
			Serequel	C	
Age:9 YR Gender:Mal Outcome Dose Duration	er: 4455155-XReport Type:E .e I/FU:I PT	Report Source	Product	Role Manufacturer	Route
Other	Hypertension	Health	Adderall Xr		
		Professional	(Amphetamine		
			Aspartate, Amphetamine Sulfate,		
			Dextroamphetamine	PS	
SEE IMAGE					
Date:09/17/04ISR Numbe Age:50 YR Gender:Mal	er: 4456622-5Report Type:E .e I/FU:F	xpedited (15-DaCompany R	eport #SUSI-2004-00453		
Outgomo					

Outcome Hospitalization -Initial or Prolonged

Freedom Of Information (FOI) Report

Other						
Required Intervention to Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Prevent Permanent Impairment/Damage	Blood Pressure Diastolic Increased Coronary Artery Occlusion Drug Tolerance Increased	Health Professional	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,			
30 MG, 1-3	Myocardial Infarction		Dextroamphetamine	PS		ORAL
CAPS QD, ORAL						
			Cialis "Lilly" (Tadalafil) Ambien (Zolpidem	С		
			Tartrate) Sonata (Zaleplon)	C C		
Date:09/24/04ISR Numbe Age:8 YR Gender:Fen	er: 4462332-0Report Type:Exped: male I/FU:F	ited (15-DaCompany Rep	ort #SUS1-2004-00425			
Age:8 YR Gender:Fen Outcome		ited (15-DaCompany Rep Report Source	ort #SUS1-2004-00425 Product	Role	Manufacturer	Route
Age:8 YR Gender:Fen	nale I/FU:F PT Electrocardiogram Abnormal Oxygen Saturation		Product Adderall Xr (Amphetamine Aspartate,	Role	Manufacturer	Route
Age:8 YR Gender:Fem Outcome Dose Duration Hospitalization - Initial or Prolonged Other	nale I/FU:F PT Electrocardiogram Abnormal	Report Source	Product Adderall Xr (Amphetamine	Role	Manufacturer	Route
Age:8 YR Gender:Fem Outcome Dose Duration Hospitalization - Initial or Prolonged	nale I/FU:F PT Electrocardiogram Abnormal Oxygen Saturation Decreased	Report Source	Product Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,	PS	Manufacturer	Route
Age:8 YR Gender:Fem Outcome Dose Duration Hospitalization - Initial or Prolonged Other	nale I/FU:F PT Electrocardiogram Abnormal Oxygen Saturation Decreased Psychiatric Symptom	Report Source	Product Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS	Manufacturer	Route

Date:09/24/04ISR Number: 4462336-8Report Type:Expedited (15-DaCompany Report #SUS1-2004-00571 Age:11 YR Gender:Male I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Convulsion	Consumer	Adderall Xr			
Other		Dyspnoea	Consumer	(Amphetamine			
		Loss Of Consciousness		Aspartate,			
		Tic		Amphetamine Sulfate,			

	Weight Decreased		Dextroamphetamine	PS	
SEE IMAGE					
			Clonidine (Clonidina)	0	
			(Clonidine) Tenex (Guanfacine	C	
			Hydrochloride)	C	
Date:09/27/04ISR Numb	per: 4462691-9Report Type:Exp	pedited (15-DaCompany R	eport #SUS1-2004-00589		
Age:31 YR Gender:Ma		· · · ·			
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration					
Required	Drug Ineffective	Consumer	Adderall(Amphetamine		
Intervention to	Fatigue		Asparatate,		
Prevent Permanent	Gastroenteritis		Amphetamine Sulfate,		
Impairment/Damage	Head Injury		Dextroamphetamine		
	Hyperhidrosis		Saccharate,	PS	
30 MG,					
	Loss Of Consciousness				
4X/DAY: QID					
	Narcolepsy		Xanax (Alprazolam)	С	
	Nausea		Zoloft (Sertraline		
	Somnolence		Hydrochloride)	С	
	Thermal Burn		Zyprexa (Olanzapine) Percocet (Oxycodone	С	
			Hydrochloride) Oxycontin (Oxycodone	С	

Freedom Of Information (FOI) Report

Hydrochloride) C

Date:09/27/04ISR Number: 4462724-XReport Type:Expedited (15-DaCompany Report #SUSI-2004-00463 Age:28 YR Gender:Male I/FU:F

Outcome	Deretion	PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat Initial or F		Asthenia Cardiomyopathy Dyspnoea Hypertension Hypoaesthesia	Consumer	Adderall Xr(Amphetamine Aspartate, Amphetatmine Sulfate,	PS		
30 MG,				Durrace,	10		
1X/DAY:QD,		Myocardial Infarction					
		Pharmaceutical Product					
UNK 10 & 30MG,		Complaint		Adderall(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Saccharate,	SS		
2X/DAY;BID,							
UNK	1840 DAY			Paxil (Paroxetine Hydrochloride)	С		
	)4ISR Number Gender:Fema	: 4462823-2Report Type:Expedit le I/FU:I	ed (15-DaCompany Repor:	t #SUSI-2004-00595			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Adrenal Carcinoma Metanephrine Urine Increased	Health Professional	Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
15 MG				Dextroampheramine	PS		
4							

Date:10/04/04ISR Number Age:11 YR Gender:Mal	r: 4467863-5Report Type:Expect e I/FU:I	lited (15-DaCompany Re	eport #SUSI-2004-00612			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Blood Pressure Decreased Dizziness	Foreign Health Professional Other	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
10 MG,			Dexcioamphecamine	ED		
1X/DAY:QD						
			Dexidrine (Dexamfetamine Sulfate) Capsule Xr	С		
			Clonidine (Clonidine)	C		
Date:10/04/04ISR Numbe Age:8 YR Gender:Fem Outcome Hospitalization - Initial or Prolonged	r: 4468122-7Report Type:Expect ale I/FU:I PT Confusional State Hallucination Hyperventilation	lited (15-DaCompany Re	eport #SUS1-2004-00604			
22-Aug-2005 10:34 AM	Overdose Panic Attack					

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Freedom Of Information (FOI) Report

		Respiratory Rate Increased Restlessness	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Skin Discolouration Tremor	Consumer	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,	DC		
10 MG,				Dextroamphetamine	PS		
Date:10/04/ Age:7 YR	04ISR Number Gender:Male	r: 4468123-9Report Type:Expe e I/FU:I	dited (15-DaCompany Re	eport #SUS1-2004-00608			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Affective Disorder Crying Depression Irritability Suicidal Ideation	Consumer	Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
SEE IMAGE		Sulcidal Ideación			PD		
				Concerta (Methylphenidate Hydrochloride) Strattera	С		
				(Tomoxetine Hydrochloride)	С		
		r: 4472444-3Report Type:Expe	dited (15-DaCompany Re	eport #SUS1-2004-00404			
Age:8 YR	Gender:Male	e I/FU:F					
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Drug Ineffective Medication Tampering Pharmaceutical Product Complaint	Other	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,			
10 MG				Dextroamphetamine	PS		

	04ISR Number Gender:Fema	: 4472525-4Report Type:Expedit le I/FU:I	ed (15-DaCompany Report	t #SUSI-2004-00626			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Death	Daracion	Alcohol Use Cardiac Arrest Hepatocellular Damage Mitral Valve Prolapse	Health Professional	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
20 MG,							
1X/DAY:QD				Dexdrine (Dexamfetamine Sulfate) Tablet	С		
	04ISR Number Gender:Male	: 4472884-2Report Type:Direct I/FU:I	Company Report	t #CTU 229285			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Pharmaceutical Product		Adderall	PS		
20 MG TID		Complaint					

Freedom Of Information (FOI) Report

Date:10/19/04ISR Number: 4480822-1Report Type:Expedited (15-DaCompany Report #SUS1-2004-00656 Age:42 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalizati	on -	Fall	Health	Adderall			
Initial or Prolonged		Intentional Misuse	Professional	(Amphetamine			
1		Medication Error		Aspartate,			
1		Oedema Peripheral		Amphetamine Sulfate,			
		Thrombosis		Dextroamphetamine	PS		
INTRAVENOUS	ONE DC	DSE,					

INTRAVENOUS

Date:10/20/04ISR Number: 4480861-0Report Type:Expedited (15-DaCompany Report #SUS1-2004-00632 Age:7 YR Gender:Female I/FU:I

Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duracion	Abnormal Behaviour Anorexia Anxiety Attention-Seeking	Consumer	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,			
		Behaviour		Dextroamphetamine	PS		
10 MG,							
		Constipation					
1X/DAY; QD,							
		Delusion					
; 5 MG,							
		Drug Ineffective					
1X/DAY; QD,		Drug Withdrawal Syndrome Fear Feeling Abnormal Heart Rate Increased Overdose Panic Reaction Psychotic Disorder Theft Urinary Incontinence					

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 5 MG 2 TABS		Drug Ineffective		Adderall - Generic	PS		ORAL
0 110 2 1120		Pharmaceutical Product					
PO BID PRN		Complaint					
Date:10/22/( Age:	04ISR Number: Gender:Male	4483731-7Report Type:Direct I/FU:I	Company Repo	rt #CTU 230233			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Drug Ineffective		Adderall 5 Mg			
5 MG 3 TABS	0	Pharmaceutical Product		Generic	PS		ORAL
0 110 0 11120	×	Complaint					
am 1 tab q i	PM						
Date:10/22/0 Age:	)4ISR Number: Gender:Femal	4483854-2Report Type:Direct .e I/FU:I	Company Repo	rt #CTU 230232			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Required Intervention 1 DAILY		Medication Error		Adderall Xr 30 Mg Rite Aid	PS	Rite Aid	ORAL
Prevent Perr ORAL	manent						
Impairment/I	Damage			Concerta 36 Mg Rite Aid	SS	Rite Aid	ODAT
1 DAILY				RICE AIQ	55	KILE AIU	ORAL
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Freedom Of Information (FOI) Report

ORAL

Date:10/22 Age:6 YR	/04ISR Number Gender:Male	r: 4483881-5Report Type:Direc e I/FU:I	t Company Rep	ort #CTU 230349			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Pharmaceutical Product Complaint		Generic Adderall 10 Mg	PS		
SEE IMAGE		Therapeutic Response Decreased					
Date:10/29 Age:7 YR	/04ISR Number Gender:Fema	r: 4492772-5Report Type:Exped ale I/FU:F	ited (15-DaCompany Rep	ort #SUSI-2004-00632			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Anorexia	Consumer	Adderall Xr			
		Anxiety		(Amphetamine			
		Attention		Aspartate,			
		Deficit/Hyperactivity		Amphetamine Sulfate,			
		Disorder		Dextroamphetmine	PS		
10 MG,							
		Constipation					
1X/DAY:QD							
		Delusion		Adderall Xr Regimen			
		Drug Withdrawal Syndrome		#2	SS		
5 MG,							
		Fear					
1X/DAY:QD							
		Feeling Abnormal					
		Grand Mal Convulsion					
		Heart Rate Increased					
		Medication Error					
		Overdose					
		Panic Attack					
		Psychotic Disorder					
		Theft					
		Tremor					
		Urinary Incontinence					

Dutcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Daractor	Herpes Zoster Initial Insomnia Overdose	Consumer	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
110 MG DAIL	Y			Effexor-Xr (Venlafaxine Hydrochloride)	С		
Date:11/02/ Age:	04ISR Number Gender:Male	: 4492407-1Report Type:Direct I/FU:I	Company Repo	rt #CTU 231096			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 20 MG TID P		Abnormal Behaviour		Adderall	PS		ORAL
	-	Drug Ineffective Pharmaceutical Product Complaint Psychomotor Hyperactivity					

Date:10/29/04ISR Number: 4492777-4Report Type:Expedited (15-DaCompany Report #SUSI-2004-00673

Freedom Of Information (FOI) Report

Date:11/02/04ISR Number: 4493403-0Report Type:Expedited (15-DaCompany Report #A0518764A Age:45 YR Gender:Female I/FU:F

Outcome Dose Durati	PT .on	Report Source	Product	Role Manufacturer	Route
Disability	Cardiomegaly Chest Pain Cough	Consumer	Dexedrine (Dextroamphetamine Sulfate)	PS	ORAL
5 MG/ SEE	Dilatation Ventricular			-	-
DOSAGE	Discomfort				
TEXT/ORAL					
	Dyspnoea Exertional Fatigue Insomnia Palpitations Pulmonary Hypertension		Adderall (Adderall) Sibutramine Hydrochloride (Sibutramine Hydrochloride)	SS	
10 MG	Furmonary mypercempron		Hydrochior rae,	66	
	Pyrexia Respiratory Distress Sensation Of Pressure Tricuspid Valve Incompetence Viral Upper Respiratory Tract Infection mber: 4495172-7Report Type:Di Male I/FU:I	.rect Company Rej	Paroxetine Hydrochloride Ciprofloxacin Lexapro Vicodin Venlafaxine Hydrochloride Diazepam		
Out name	PT	Report Source	Product	Role Manufacturer	Route
Outcome Dose Durati	on				
	on Drug Ineffective		Adderall (Mixed Dextroamphetamine)(G	DO	
				PS	
Dose Durati			Dextroamphetamine)(G	PS	

Date:11/12/04ISR Number: 4502721-9Report Type:Expedited (15-DaCompany Report #SUS1-2004-00632 Age:7 YR Gender:Female I/FU:F

Dutcome Dose	Duration	PT	Report Source	Product	ROIE	Manufacturer	Route
Disability		Abnormal Behaviour	Consumer	Adderall Xr (See			
Other SEE IMAGE		Anxiety	Health	Image)	PS		
		Attention Deficit/Hyperactivity Disorder Constipation Delusion Disease Recurrence Drug Withdrawal Syndrome Fear Feeling Abnormal Grand Mal Convulsion Heart Rate Increased Oral Intake Reduced Overdose Panic Reaction Psychotic Disorder Refusal Of Treatment By Relative Theft Tonic Convulsion Urinary Incontinence	Professional				

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:11/16/04ISR Number: 4502929-2Report Type:Direct Company Report #CTU 232187 Age: Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Chest Pain Adderall Extended Other Crying Release 10mg PS 10 MG 1X Headache DAILY Irritability Concerta Extended Mood Altered Release 27mg SS 27MG 1X DAILY Pallor Thirst Date:11/16/04ISR Number: 4504249-9Report Type:Expedited (15-DaCompany Report #S04-USA-07340-01 Age: Gender:Male I/FU:I  $\mathbf{PT}$ Outcome Report Source Product Role Manufacturer Route Dose Duration Hospitalization -Agitation Health Lexapro Initial or Prolonged Delusion Professional (Escitalopram) PS Adderall SS Drug Interaction Hallucination Date:11/18/04ISR Number: 4505420-2Report Type:Direct Company Report #CTU 232391 Age:6 YR Gender:Female I/FU:I  $\mathbf{PT}$ Role Manufacturer Outcome Report Source Product Route Dose Duration Hospitalization -Dyskinesia Adderall Xr 10 Mg PS ORAL 10 MG DAILY Initial or Prolonged Trance ORAL Date:11/18/04ISR Number: 4507413-8Report Type:Expedited (15-DaCompany Report #SUSI-2004-00722 Age:10 YR Gender:Male I/FU:I PTReport Source Product Role Manufacturer Route Outcome

Dose

Duration

Hospitalization - Initial or Prolonged	Dysarthria Feeling Abnormal Paraesthesia Paralysis	Health Professional	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		ORAL
5 MG,			Descroamprictamine	ID		ONAL
1X/DAY:QD,						
ORAL			Zyrtec (Cetirizine Hydrochooride) Syrup	С		
Date:11/19/04ISR Numbe Age: Gender:Fem	er: 4512878-1Report Type:Direct male I/FU:I	Company Rep	port #CTU 232506			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Other ONE PILL	Mouth Ulceration		Adderall 30 Mg	PS		
DAILY	Pharmaceutical Product					
	Complaint					
Date:11/19/04ISR Numbe Age:32 YR Gender:Fem	er: 4512924-5Report Type:Direct male I/FU:I	Company Rep	port #CTU 232487			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - 40 MG BID Initial or Prolonged	Dystonia		Cymbalta 40 Mg	PS		ORAL
oral 5 mg qd oral			Aderall 5 Mg	SS		ORAL
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Freedom Of Information (FOI) Report

Date:11/24/04ISR Number: 4510419-6Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0518764A Age:45 YR Gender:Female I/FU:F

Outcome	Dunnation	PT	Report Source	Product	Role	Manufacturer	Route
Dose Disability 5MG See	Duration	Cardiomegaly	Other	Dexedrine	PS	Glaxosmithkline	ORAL
		Chest Discomfort					
dosage text							
		Chest Pain		Adderall	SS		
		Cough		Meridia	SS	~	
OFMO Der der		Dilatation Ventricular		Paxil Cr	С	Glaxosmithkline	
25MG Per day		Dyspnoea Exertional		Ciprofloxacin	С		
		Fatigue		Lexapro	C		
		Insomnia		Vicodin	C		
		Palpitations		Effexor	C		
		Pulmonary Hypertension		Diazepam	C		
		Pyrexia			-		
		Respiratory Distress					
		Tricuspid Valve					
		Incompetence					
	4ISR Number Gender:Male	r: 4514205-2Report Type:Expe e I/FU:F	edited (15-DaCompany Re	eport #SUS1-2004-00571			
Age:11 YR Outcome	Gender:Male		edited (15-DaCompany Re Report Source	eport #SUS1-2004-00571 Product	Role	Manufacturer	Route
Age:11 YR Outcome Dose		e I/FU:F PT	Report Source	Product	Role	Manufacturer	Route
Age:11 YR Outcome Dose Disability	Gender:Male	PT Convulsion	Report Source Consumer	Product Adderall	Role	Manufacturer	Route
Age:11 YR Outcome Dose	Gender:Male	PT Convulsion Drooling	Report Source Consumer Health	Product Adderall Xr(Amphetamine	Role	Manufacturer	Route
Age:11 YR Outcome Dose Disability	Gender:Male	e I/FU:F PT Convulsion Drooling Drug Hypersensitivity	Report Source Consumer	Product Adderall Xr(Amphetamine Aspartate,	Role	Manufacturer	Route
Age:11 YR Outcome Dose Disability	Gender:Male	e I/FU:F PT Convulsion Drooling Drug Hypersensitivity Dyskinesia	Report Source Consumer Health	Product Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate,		Manufacturer	Route
Age:11 YR Outcome Dose Disability Other	Gender:Male	e I/FU:F PT Convulsion Drooling Drug Hypersensitivity	Report Source Consumer Health	Product Adderall Xr(Amphetamine Aspartate,	Role PS	Manufacturer	Route
Age:11 YR Outcome Dose Disability	Gender:Male	e I/FU:F PT Convulsion Drooling Drug Hypersensitivity Dyskinesia Educational Problem	Report Source Consumer Health	Product Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate,		Manufacturer	Route
Age:11 YR Outcome Dose Disability Other 10 & 20 MG,	Gender:Male	e I/FU:F PT Convulsion Drooling Drug Hypersensitivity Dyskinesia	Report Source Consumer Health	Product Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate,		Manufacturer	Route
Age:11 YR Outcome Dose Disability Other	Gender:Male	e I/FU:F PT Convulsion Drooling Drug Hypersensitivity Dyskinesia Educational Problem	Report Source Consumer Health	Product Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate,		Manufacturer	Route
Age:11 YR Outcome Dose Disability Other 10 & 20 MG,	Gender:Male	e I/FU:F PT Convulsion Drooling Drug Hypersensitivity Dyskinesia Educational Problem Headache	Report Source Consumer Health	Product Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS	Manufacturer	Route
Age:11 YR Outcome Dose Disability Other 10 & 20 MG,	Gender:Male	e I/FU:F PT Convulsion Drooling Drug Hypersensitivity Dyskinesia Educational Problem Headache Incoherent	Report Source Consumer Health	Product Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Clonidine		Manufacturer	Route
Age:11 YR Outcome Dose Disability Other 10 & 20 MG,	Gender:Male	PT Convulsion Drooling Drug Hypersensitivity Dyskinesia Educational Problem Headache Incoherent Loss Of Consciousness	Report Source Consumer Health	Product Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Clonidine (Clonidine) Patch	PS	Manufacturer	Route
Age:11 YR Outcome Dose Disability Other 10 & 20 MG,	Gender:Male	PT Convulsion Drooling Drug Hypersensitivity Dyskinesia Educational Problem Headache Incoherent Loss Of Consciousness Sleep Disorder	Report Source Consumer Health	Product Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Clonidine (Clonidine) Patch	PS	Manufacturer	Route
Age:11 YR Outcome Dose Disability Other 10 & 20 MG,	Gender:Male	PT Convulsion Drooling Drug Hypersensitivity Dyskinesia Educational Problem Headache Incoherent Loss Of Consciousness Sleep Disorder Tic	Report Source Consumer Health	Product Adderall Xr(Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Clonidine (Clonidine) Patch	PS	Manufacturer	Route

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Other	Accidental Overdose	Consumer	Adderall			
	Cardiac Fibrillation		Xr(Amphetamine			
	Medication Error		Aspartate,			
	Nervousness Restlessness		Amphetamine Sulfate,	PS		
SEE IMAGE	RESCIESSIESS		Dextroamphetamine	PS		
SEE IMAGE						
Date:11/26/04ISR Numbe Age:60 YR Gender:Ma	er: 4514209-XReport Type:Exped le I/FU:I	ited (15-DaCompany Re	eport #SUS1-2004-00753			
Age:60 YR Gender:Ma Outcome	le I/FU:I PT	ited (15-DaCompany Re Report Source	eport #SUS1-2004-00753 Product	Role	Manufacturer	Route
Age:60 YR Gender:Ma Outcome Dose Duration	le I/FU:I PT		-	Role	Manufacturer	Route
Age:60 YR Gender:Ma Outcome Dose Duration Hospitalization -	le I/FU:I PT	Report Source	Product	Role	Manufacturer	Route
Age:60 YR Gender:Ma Outcome Dose Duration	le I/FU:I PT Apraxia	Report Source	Product Adderall Xr	Role	Manufacturer	Route
Age:60 YR Gender:Ma Outcome Dose Duration Hospitalization - Initial or Prolonged	le I/FU:I PT Apraxia Cerebrovascular Accident	Report Source	Product Adderall Xr (Amphetamine	Role	Manufacturer	Route
Age:60 YR Gender:Ma Outcome Dose Duration Hospitalization - Initial or Prolonged Other	le I/FU:I PT Apraxia Cerebrovascular Accident Dizziness	Report Source	Product Adderall Xr (Amphetamine Aspartate,	Role	Manufacturer	Route
Age:60 YR Gender:Ma Outcome Dose Duration Hospitalization - Initial or Prolonged	le I/FU:I PT Apraxia Cerebrovascular Accident Dizziness Intracranial Aneurysm	Report Source	Product Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,		Manufacturer	Route
Age:60 YR Gender:Mai Outcome Dose Duration Hospitalization - Initial or Prolonged Other 15 MG,	le I/FU:I PT Apraxia Cerebrovascular Accident Dizziness Intracranial Aneurysm	Report Source	Product Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,		Manufacturer	Route
Age:60 YR Gender:Ma Outcome Dose Duration Hospitalization - Initial or Prolonged Other	le I/FU:I PT Apraxia Cerebrovascular Accident Dizziness Intracranial Aneurysm	Report Source	Product Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate,		Manufacturer	Route

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:11/26/04ISR Number: 4514240-4Report Type:Expedited (15-DaCompany Report #SUSI-2004-00749 Age:15 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Cardiac Fibrillation Consumer Adderall (Amphetamine Heart Rate Increased Aspartate, Amphetamine Sulfate, Dextroamphetamine Saccharate, PS 10 MG, 2X/DAY; BID, UNK Date:11/30/04ISR Number: 4513645-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0522659A Gender:Female Age:42 YR I/FU:F Outcome PTReport Source Product Role Manufacturer Route Dose Duration Life-Threatening Grand Mal Convulsion Wellbutrin PS Glaxosmithkline ORAL MON Alcohol Other SS Adderall SS Celexa С 60MG Per day Date:11/30/04ISR Number: 4513941-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0528476A I/FU:I Age: Gender: Outcome PTReport Source Product Role Manufacturer Route Dose Duration Glaxosmithkline ORAL Drug Interaction Wellbutrin Xl PS 300MG Unknown Tachycardia Adderall Xr SS UNKNOWN 10MG Unknown

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalizat Initial or F		Agitation Delusion Drug Interaction Hallucination	Health Professional	Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Lexapro (Escitalopram	PS		
				Oxalate) Tablet	SS		
	)4ISR Number Gender:Male	: 4518987-5Report Type: I/FU:I	Direct Company Re	eport #CTU 233647			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate		Cardiac Disorder Dyspnoea Rash Generalised		Adderall 25mg	PS		
	Gender:Fema		Expedited (15-DaCompany Re	port #SUSI-2004-00774			
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Freedom Of Information (FOI) Report

		Overdose Thinking Abnormal					
Dose	Duration	2	Report Source	Product	Role	Manufacturer	Route
	Duration		Consumer	Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
SEE IMAGE				Adderall (Amphetamine Aspartate, Amphetamine Sulfate,			
160 MG				Dextroamphetamine	SS		
Age:6 MON (	4ISR Number Gender:Male		Company Repor				
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate		Cardiac Disorder Cardiac Operation Cyanosis Loss Of Consciousness Skin Discolouration		Adderal Xr 25mg	PS		
	4ISR Number Gender:Femal	: 4526793-0Report Type:Expedit le I/FU:I	ed (15-DaCompany Repor	t #SUS1-2004-00801			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duración	Dizziness Loss Of Consciousness Respiratory Rate Increased Syncope	Consumer	Adderall Xr(Dextroamphetamine Sulfate, Dextroamphetamine Saccharate,	PS		
		Thinking Abnormal		baccharace,	гIJ		

Date:12/14/( Age:11 YR		: 4527317-4Report Type:Direct I/FU:I		Company Repor	t #CTU 234265				
Outcome		PT	Report	Source	Product		Role	Manufacturer	Route
Dose	Duration	Drug Ineffective			Adderall Xr	20mg	PS		
ONCE DAILY		-				_			
ONCE DAILY					Concerta 2	7mg	SS		
	)4ISR Number: Gender:Male	: 4527322-8Report Type:Direct I/FU:I		Company Repor	t #CTU 234304				
Outcome	Dunchian	PT	Report	Source	Product		Role	Manufacturer	Route
Dose Other 1 2X DAILY	Duration	Anorexia			Depakote Er	500 Mg	PS		ORAL
0		Asthenia							
ORAL 1 1X DAILY		Feeling Cold			Adderall Xr	20 Mg	SS		ORAL
ORAL		International Normalised							
		Ratio Increased Pallor Prothrombin Time Prolonged Weight Decreased							

Freedom Of Information (FOI) Report

Date:12/22/04ISR Number: 4539062-XReport Type:Expedited (15-DaCompany Report #SUSI-2004-00500 Age:14 YR Gender:Female I/FU:F

Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other SEE IMAGE	Duration	Asthma Cough Throat Irritation	Consumer	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
	)4ISR Number Gender∶Male	: 4539064-3Report Type:Exped	lited (15-DaCompany Rep	port #SUSI-2004-00864			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or F	cion -	Convulsion Headache Personality Change Psychotic Disorder Vomiting	Health Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine Saccharate,Amphetami	PS		
Date:12/28/0 Age:9 YR	)4ISR Number Gender:Male	: 4539459-8Report Type:Direc I/FU:I	t Company Rep	port #USP 57010			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
CAPSULE	Duración	Medication Error		Adderall Xr	PS		
CAPSULE				Adderall Xr	SS		
	)5ISR Number Gender:Male	: 4545209-1Report Type:Direc I/FU:I	t Company Rep	port #CTU 235472			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
1 DAILY	Duración	Drug Ineffective		Adderall Xr 20 Mg	PS		

1 DAILY

Concerta 27 Mg SS

Date:01/04/05ISR Number: 4544131-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0518764A Age:45 YR Gender:Female I/FU:F

Outcome	Dunchion	PT	Report Source	Product	Role	Manufacturer	Route
Dose Disability 5MG See	Duration	Anxiety		Dexedrine	PS	Glaxosmithkline	ORAL
		Cardiomegaly					
dosage text							
		Chest Discomfort		Adderall	SS		
		Chest Pain		Meridia	SS		
		Cough		Paxil Cr	С	Glaxosmithkline	
25MG Per day							
		Dilatation Ventricular		Ciprofloxacin	С		
		Dyspnoea Exertional		Lexapro	С		
		Fatigue		Vicodin	С		
		Insomnia		Effexor	С		
		Palpitations		Diazepam	С		
		Pulmonary Hypertension					
		Pyrexia					
		Respiratory Distress					
		Tricuspid Valve					
		Incompetence					
		Viral Upper Respiratory					
		Tract Infection					

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:01/05/05ISR Number: 4548074-1Report Type:Direct Company Report #CTU 235641 Age:35 YR Gender:Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Life-Threatening Activities Of Daily Adderall Xr 10mg Living Impaired PS ORAL Disability Shire Shire 10MG ONCE Anxiety DAILY ORAL Zoloft Depression С Hypomania Tegretol С Ill-Defined Disorder Impaired Self-Care Date:01/10/05ISR Number: 4565113-2Report Type:Direct Company Report #CTU 236097 Gender:Female I/FU:I Age: Role Manufacturer Outcome PTReport Source Product Route Dose Duration Disorientation Adderall Brand Name Disturbance In Attention Med Nec. PS ORAL 20 MG ONE PO Disturbance In Social Q AM Behaviour Educational Problem Date:01/12/05ISR Number: 4563894-5Report Type:Direct Company Report #CTU 236281 Age:6 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Abnormal Behaviour Adderall ORAL Other PS 5 MG TWO PO Required Condition Aggravated AM AND 1 PO Intervention to Pharmaceutical Product ΡМ Prevent Permanent Complaint Impairment/Damage

	5ISR Number Gender:Male	: 4606747-6Report Type: I/FU:I	Periodic	Company Report	#HQWYE766306DEC04			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other		Blood Pressure Increas Tachycardia	sed Consume		Effexor (Venlafaxine Hydrochloride, Tablet) Adderall (Amfetamine Aspartate/Amfetamine Sulfate/Dexamfetamin e	PS		
					Saccharate/Dexamfeta Suboxone (Buprenorphine Hydrochloride/Naloxo	SS		
SUBLINGUAL	0 MG 11	X PER 1			ne Hydrochloride, )	SS		
SUBLINGUAL	8 MG 12	X PER 1						
DAY,								
SUBLINGUAL								
	5ISR Number Gender:Male	: 4556677-3Report Type: I/FU:I	Expedited (15-1	DaCompany Report	#SUS1-2005-00002			
Outcome		PT						
Other		Agitation Anger Blood Pressure Increas	sed					
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Freedom Of Information (FOI) Report

		Irritability Mania					
Dose	Duration	Paranoia	Report Source	Product	Role	Manufacturer	Route
	241401011	Psychotic Disorder	Consumer	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine			
25 MG,				Saccharate,	PS		
1X/DAY; QD							
QAM							
				Propecia (Finasteride)	С		
	5ISR Number Gender:Fema	: 4556682-7Report Type:Expedite le I/FU:I	ed (15-DaCompany Report	#SUSI-2005-00013			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Electrocardiogram Qt Corrected Interval Prolonged Sinus Tachycardia	Health Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine	DC		
15 MG,				Saccharate,	PS		
1X/DAY; QD							
	5ISR Number Gender:	: 4556685-2Report Type:Expedit	ed (15-DaCompany Report	#SUS1-2005-00015			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Hospitalizat Initial or P Required Intervention Prevent Perm	rolonged to	Anoxia Cardiac Disorder Circulatory Collapse Encephalopathy Movement Disorder	Health Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine Saccharate,	DS		
Prevent Perm 10 MG,	allellt	Movement Disorder		Saccharale,	PS		

Impairment/Dam 1X/DAY:QD	mage	Nervous System Disorder					
		Ventricular Fibrillation					
	ISR Number: ender:Male	: 4556688-8Report Type:Expedit I/FU:I	ted (15-DaCompany Repo	rt #SUS1-2005-00018			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose I Other		Amnesia Migraine Simple Partial Seizures Sinus Headache	Consumer	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine			
				Saccharate,	PS		
	ISR Number: ender:Male	: 4679201-3Report Type:Direct I/FU:I	Company Repo	ort #CTU 237244			
Outcome Other		PT Aggression					
		Condition Aggravated Oppositional Defiant Disorder					
		Psychomotor Hyperactivity Therapeutic Response Unexpected With Drug					
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Freedom Of Information (FOI) Report

Substitution Role Manufacturer Report Source Product Route Duration Dose Generic Adderall PS 300 MG TWICE DAILY Date:01/20/05ISR Number: 4559956-9Report Type:Direct Company Report #CTU 237267 Age: Gender: I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Drug Ineffective Adderal PS Other Pharmaceutical Product Complaint Date:01/26/05ISR Number: 4565620-2Report Type:Expedited (15-DaCompany Report #SUS1-2005-00026 Gender:Female I/FU:I Age:15 YR Report Source Product Role Manufacturer Outcome PTRoute Dose Duration Life-Threatening Irritability Adderall Consumer Overdose Xr(Detroamphetamine Sulfate, Dextroamphetamine Saccharate, PS Date:01/26/05ISR Number: 4566369-2Report Type:Direct Company Report #CTU 238176 Aqe:19 YR Gender:Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Cognitive Disorder Adderall Xr 10 Feeling Drunk Shire Us PS Shire Us ORAL 10 Ο ΑΜ ORAL Synthroid С

Prozac

С

Age: Gender:Male	r: 4575389-3Report Type:Direct e I/FU:I	Company Rep	ort #CTU 238653			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
20 MG TID -	Agitation		Adderall (Generics	PS		
QID 7 YR	Drug Ineffective Pharmaceutical Product Complaint		Buspirone (Generic (30mg Bid) (4 Yrs)	SS		
10 MG TID -						
QID						
Age:20 YR Gender:Mal	r: 4571902-0Report Type:Exped:	LLEG (15-Dacompany Rep	016 #2021-2002-00032			
Outcome	e I/FU:I PT	Report Source	Product	Role	Manufacturer	Route
Outcome Dose Duration Hospitalization - Initial or Prolonged Other	PT Aggression Drug Withdrawal Syndrome Nerve Injury	Report Source Consumer	Product Adderall Xr (Dextroamphetamine Sulfate,	Role	Manufacturer	Route
Outcome Dose Duration Hospitalization - Initial or Prolonged Other Required Intervention to	PT Aggression Drug Withdrawal Syndrome	-	Product Adderall Xr (Dextroamphetamine	Role PS	Manufacturer	Route
Outcome Dose Duration Hospitalization - Initial or Prolonged Other Required Intervention to 30 MG, Prevent Permanent	PT Aggression Drug Withdrawal Syndrome Nerve Injury Nightmare	-	Product Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine		Manufacturer	Route
Outcome Dose Duration Hospitalization - Initial or Prolonged Other Required Intervention to 30 MG,	PT Aggression Drug Withdrawal Syndrome Nerve Injury Nightmare Restlessness	-	Product Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine		Manufacturer	Route

Freedom Of Information (FOI) Report

Hydrochloride) С

Date:02/02/05ISR Number: 4571903-2Report Type:Expedited (15-DaCompany Report #SUSI-2004-00862 Age:6 YR Gender:Male I/FU:I

Outcome	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Panic Attack	Health Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine Saccharate,	PS		ORAL
25 MG,				Saccharate,	r9		URAU
1X/DAY;QD,							
ORAL				Strattera (Atomoxetine Hydrochloride) Fluoride	C C		
Date:02/02/ Age:13 YR	05ISR Number Gender:Male	r: 4571908-1Report Type:Exp e I/FU:I	edited (15-DaCompany R	eport #SUSI-2005-00036			
Outcome Dose	Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duracion	Abasia Condition Aggravated Muscle Spasticity Pain	Consumer	Adderall Xr (Dextromaphetamine Sulfate, Dextroamphetamine Sacchartate,	τC		ORAL
15 MG,				Sacchartate,	PS		UKAL
1X/DAY; QD,							
ORAL							
				Concerta (Methylphenidate			

(methy)phenidate Hydrochloride)

С

	r: 4571931-7Report Type:Exped	ited (15-DaCompany Re	eport #SUS1-2005-00044			
Age:9 YR Gender:Male	e I/FU:I					
Outcome Dose Duration	РТ	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Aggression Hallucination, Auditory Self Injurious Behaviour	Consumer	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine Saccharate,	PS		
SEE IMAGE			Saccharace,	FD		

Date:02/02/05ISR Number: 4571934-2Report Type:Expedited (15-DaCompany Report #SUS1-2004-00571 Age:11 YR Gender:Male I/FU:F

Outcome PT Disability Convulsion Other Decreased Appetite Drooling Drug Hypersensitivity Drug Ineffective Dyspnoea Fall Headache Incoherent Lethargy Loss Of Consciousness

Freedom Of Information (FOI) Report

Dose SEE IMAGE	Duration	Movement Disorder Rash Reaction To Medical Agent Preservatives Sleep Disorder Social Avoidant Behaviour Streptococcal Infection Tic Tourette'S Disorder Weight Decreased	Report Source Consumer Health Professional	Product Adderall Xr (Amhpetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Clonidine (Clonidine) Tenex	Role PS C C	Manufacturer	Route
Date:02/02/ Age:	05ISR Number Gender:Male	r: 4578024-3Report Type:Direct	Company Repor	rt #CTU 239010			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose 1 PO TID	Duration	Pharmaceutical Product Complaint		Adderal 10 Mg	PS		ORAL
Date:02/02/ Age:7 YR	05ISR Number Gender:Fema	r: 4578121-2Report Type:Direct ale I/FU:I	Company Repor	rt #CTU 238852			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Drug Ineffective Irritability Pharmaceutical Product Complaint		Adderall	PS		
Date:02/02/ Age:7 YR	05ISR Number Gender:Fema	r: 4578319-3Report Type:Direct ale I/FU:I	Company Repor	rt #CTU 238861			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duración	Drug Ineffective Irritability Pharmaceutical Product		Adderall	PS		

Complaint
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Age: Gender		4571635-0Report Type:Direct I/FU:I		Company Report	: #CTU 239103			
Outcome Dose Durat 20 MG 1/2 TAB BID	Ph Cc	T harmaceutical Product omplaint herapy Non-Responder	Report		Product Adderall 20 Mg	Role PS	Manufacturer :	Route
								L.
	umber: 4 :Female	4571649-0Report Type:Direct I/FU:I		Company Report	: #CTU 239110			
Age: Gender Outcome	:Female	I/FU:I	Report		F #CTU 239110 Product	Role	Manufacturer 3	Route
Age: Gender	:Female PI ion	I/FU:I	Report	Source		Role PS		Route ORAL

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:02/03/05ISR Number: 4572027-0Report Type:Direct Company Report #CTU 239133 Gender:Male I/FU:I Age: Report Source Role Manufacturer Outcome PTProduct Route Duration Dose Agitation Adderall (Generics) PS 20 MG TID -Drug Ineffective YR QID 7 Pharmaceutical Product Buspirone (Generic Complaint (30mg Bid) (4yrs SS 10 MG TID -QID Lamictal С Risperdal С Date:02/08/05ISR Number: 4573503-7Report Type:Periodic Company Report #SUS1-2004-00497 Gender:Female Aqe:30 YR I/FU:I Report Source Role Manufacturer Outcome PTProduct Route Dose Duration Hospitalization -Abnormal Behaviour Paxil PS Glaxosmithkline ORAL 20MG Per day MON 18 Initial or Prolonged Adderall Xr ORAL Delusion SS 30MG Per day Hallucination, Auditory Mania Psychotic Disorder Refusal Of Treatment By Patient Date:02/08/05ISR Number: 4574550-1Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0443491A Age:13 YR Gender:Male I/FU:F Outcome PTReport Source Product Role Manufacturer Route Dose Duration Gingival Hyperplasia Paxil PS Glaxosmithkline ORAL Adderall SS

ISR Number:	: 4578793-2Report Type:Direct	Co	ompany Repor	t #CTU 239974				
ender:Male	I/FU:I							
Duration	PT	Report Sou	ırce	Product		Role	Manufacturer	Route
	Drug Effect Decreased Irritability			Adderall 5 Mg (Generic)		PS		ORAL
	Pharmaceutical Product Complaint			Abilify		С		
ISR Number: ender:Male	: 4582466-XReport Type:Direct I/FU:I	Cc	ompany Repor	t #CTU 240261				
	PT	Report Sou	ırce	Product		Role	Manufacturer	Route
	Heart Rate Increased Impulsive Behaviour			Adderall Xr Shire	10mg	PS	Shire	ORAL
		Co	ompany Repor	t #CTU 240260				
	ender:Male Duration USR Number ender:Male Duration USR Number ender:Fema: ing on - olonged	PT Duration Drug Effect Decreased Irritability Pharmaceutical Product Complaint USR Number: 4582466-XReport Type:Direct I/FU:I PT Duration Heart Rate Increased Impulsive Behaviour USR Number: 4582468-3Report Type:Direct ender:Female I/FU:I ing on - olonged 10	ender:Male I/FU:I PT Report Sou Drug Effect Decreased Irritability Pharmaceutical Product Complaint USR Number: 4582466-XReport Type:Direct Complaint ESR Number: 4582466-XReport Type:Direct Complexity PT Report Sou Heart Rate Increased Impulsive Behaviour ESR Number: 4582468-3Report Type:Direct Complexity ender:Female I/FU:I Complexity Complexity Complexity Complexity Complexity PT Report Sou Heart Rate Increased Impulsive Behaviour Complexity Comp	ender:Male I/FU:I PT Report Source Drug Effect Decreased Irritability Pharmaceutical Product Complaint USR Number: 4582466-XReport Type:Direct Company Repor ender:Male I/FU:I PT Report Source Heart Rate Increased Impulsive Behaviour USR Number: 4582468-3Report Type:Direct Company Repor ender:Female I/FU:I Company Report Company Report Company Report Company Report Company Report Company Report PT Company Repo	ender:Male I/FU:I PT Report Source Product Drug Effect Decreased Irritability (Generic) Pharmaceutical Product Complaint Abilify USR Number: 4582466-XReport Type:Direct Company Report #CTU 240261 ender:Male I/FU:I Duration PT Report Source Product Meart Rate Increased Adderall Xr Impulsive Behaviour Shire ESR Number: 4582468-3Report Type:Direct Company Report #CTU 240260 Heart Rate Increased Adderall Xr Shire Shire ESR Number: 4582468-3Report Type:Direct Company Report #CTU 240260 Hongon - slonged Heart Rate Increased Company Report #CTU 240260 Heart Rate Increased Company Report #CTU 240260 PT PT P	ender:Male I/FU:I PT Report Source Product Drug Effect Decreased Adderall 5 Mg (Generic) Pharmaceutical Product Complaint USR Number: 4582466-XReport Type:Direct Company Report #CTU 240261 ender:Male I/FU:I PT Report Source Product Heart Rate Increased Adderall Xr 10mg Impulsive Behaviour Shire USR Number: 4582468-3Report Type:Direct Company Report #CTU 240260 ESR Number: 4582468-3Report PSR Number Company Report #CTU 240260 ESR Number	ender:Male I/FU:I PT Report Source Product Role Drug Effect Decreased Adderall 5 Mg (Generic) PS Pharmaceutical Product Abilify C Complaint C Company Report #CTU 240261 I/FU:I Report Source Product Role Heart Rate Increased Adderall Xr 10mg Shire PS Shire PS ESR Number: 4582468-3Report Type:Direct Company Report #CTU 240260 Heart Rate Increased Adderall Xr 10mg Shire PS Shire PS ESR Number: 4582468-3Report Type:Direct Company Report #CTU 240260 Heart Rate Increased I/FU:I	ander:Male I/FU:I PT Report Source Product Role Manufacturer Drug Effect Decreased Irritability (Generic) PS Pharmaceutical Product Complaint Abilify C StR Number: 4582466-XReport Type:Direct Company Report #CTU 240261 Irritability I/FU:I PT Report Source Product Role Manufacturer Heart Rate Increased Impulsive Behaviour PS Shire PS Shire Stree I/FU:I StR Number: 4582468-3Report Type:Direct Company Report #CTU 240260 ender:Female I/FU:I

Freedom Of Information (FOI) Report

Prevent Permanent Impairment/Damage PTReport Source Product Role Manufacturer Route Dose Duration Convulsion Adderall 20 Mg Hyperventilation Shire Pharm PS Shire Pharm ORAL 20 MG Q.D. Respiratory Failure ORAL Tachycardia Date:02/11/05ISR Number: 4582597-4Report Type:Direct Company Report #CTU 240176 Aqe: Gender:Male I/FU:I Report Source Role Manufacturer Outcome PTProduct Route Duration Dose Drug Effect Decreased Adderall 5 Mg Pharmaceutical Product (Generic Amphetamine Complaint Salts) PS ORAL ONE PO Q AM Date:02/14/05ISR Number: 4581842-9Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0503390A Gender:Female I/FU:I Age: PTReport Source Product Role Manufacturer Outcome Route Dose Duration Sinusitis Lamotrigine PS Glaxosmithkline 50MG Per day Adderall Xr SS 15MG Per day Date:02/14/05ISR Number: 4589157-XReport Type:Direct Company Report #CTU 240349 Age: Gender:Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Life-Threatening Amaurosis Fugax Adderall Xr 20 Mg PS DAILY Hospitalization -Transient Ischaemic Initial or Prolonged Attack

	5ISR Number: Gender:Male	4589152-OReport Type:Direct I/FU:I	Company Repor	t #CTU 240387			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 1 PILL A DAY	Duration	Convulsion		Adderall	PS		
		Muscle Twitching Tremor					
	5ISR Number: Gender:Male	4589161-1Report Type:Direct I/FU:I	Company Repor	t #CTU 240388			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Chest Pain		Adderall 15mg			
15MG 1		Palpitations		Shire Usinc.	PS	Shire Usinc	ORAL
CAPSULE ORAL							
Date:02/16/0 Age:45 YR		4584178-5Report Type:Expedit Le I/FU:F	ed (15-DaCompany Repor	t #US-GLAXOSMITHKLINE-	A05187	64A	
Outcome Disability		PT Cardiomegaly Chest Discomfort Chest Pain Cough					
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Freedom Of Information (FOI) Report

Dogo	Duration	Dilatation Ventricular Dyspnoea Exertional Fatigue	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Insomnia		Dexedrine	PS	Glaxosmithkline	ORAL
5MG See							-
		Palpitations					
dosage text		Pericardial Effusion		Adderall	SS		
		Pericardial Ellusion Pulmonary Hypertension		Meridia	SS		
		Pyrexia		Paxil Cr	C	Glaxosmithkline	
25MG Per day	У				5	0101102	
-	<b>L</b>	Respiratory Distress		Ciprofloxacin	С		
		Tricuspid Valve		Lexapro	С		
I		Incompetence		Vicodin	C		
				Effexor	C		
				Diazepam	С		
Age:9 YR Outcome	Gender:Fema	r: 4588451-6Report Type:Direct ale I/FU:I PT	Report Source	ort #CTU 240482 Product	Role	Manufacturer	Route
Dose Other 5 MG -1 1/2 AM 1 1/2 Q H , 1 Q AM		Pharmaceutical Product Complaint		Adderall (Daw)	PS	Daw	Nouce
Other 5 MG -1 1/2 AM 1 1/2 Q B , 1 Q AM	Q PM 05ISR Number	Complaint c: 4588459-0Report Type:Direct	. Company Rep				Nouce
Other 5 MG -1 1/2 AM 1 1/2 Q H , 1 Q AM Date:02/16/0 Age:13 YR Outcome	Q PM 05ISR Number Gender:Fema	Complaint c: 4588459-0Report Type:Direct	Company Rep Report Source	Adderall (Daw)	PS		Route
Other 5 MG -1 1/2 AM 1 1/2 Q H , 1 Q AM Date:02/16/0 Age:13 YR Outcome Dose Other	Q PM 05ISR Number	Complaint c: 4588459-0Report Type:Direct ale I/FU:I		Adderall (Daw) ort #CTU 240485	PS	Daw	
Other 5 MG -1 1/2 AM 1 1/2 Q H , 1 Q AM Date:02/16/0 Age:13 YR Outcome Dose Other	Q PM 05ISR Number Gender:Fema	Complaint c: 4588459-0Report Type:Direct ale I/FU:I PT		Adderall (Daw) ort #CTU 240485 Product	PS Role	Daw Manufacturer	
Other 5 MG -1 1/2 AM 1 1/2 Q H , 1 Q AM Date:02/16/0 Age:13 YR	Q PM 05ISR Number Gender:Fema	Complaint Complaint r: 4588459-0Report Type:Direct ale I/FU:I PT Drug Ineffective		Adderall (Daw) ort #CTU 240485 Product	PS Role	Daw Manufacturer	

Date:02/	16/0	)5ISR	Number:	4589258-6Report	Type:Expedited	(15-DaCompany	Report	#SUSI-2005-00092	
Age:49 Y	R	Gende	r:Female	I/FU:I					

PT	Report Source	Product	Role	Manufacturer	Route
Crohn'S Disease	Health Professional	Adderall (Dextroamphetamine Sulfate, Dextroamphetamine	DC		
		Saccharace,	PD		
		Strattera (Atomoxetine Hydrochloride) Elavil (Amitriptyline Hydrochloride) Aricept (Donepezil Hydrochloride) Wellbutrin (Bupropion Hydrochloride) Prozac (Fluoxetine Hydrochloride)	C C C C		
		Crohn'S Disease Health	Crohn'S Disease Health Professional Adderall (Dextroamphetamine Sulfate, Dextroamphetamine Saccharate, Strattera (Atomoxetine Hydrochloride) Elavil (Amitriptyline Hydrochloride) Aricept (Donepezil Hydrochloride) Wellbutrin (Bupropion Hydrochloride) Prozac (Fluoxetine	Crohn'S Disease Health Professional Adderall (Dextroamphetamine Sulfate, Dextroamphetamine Saccharate, PS Strattera (Atomoxetine Hydrochloride) C Elavil (Amitriptyline Hydrochloride) C Elavil (Amitriptyline Hydrochloride) C Wellbutrin (Bupropion Hydrochloride) C Wellbutrin	Crohn'S Disease Health Adderall Professional (Dextroamphetamine Sulfate, Dextroamphetamine Saccharate, PS Strattera (Atomoxetine Hydrochloride) C Elavil (Amitriptyline Hydrochloride) C Aricept (Donepezil Hydrochloride) C Aricept (Donepezil Hydrochloride) C Wellbutrin (Bupropion Hydrochloride) C Wellbutrin (Bupropion Hydrochloride) C

Freedom Of Information (FOI) Report

Date:02/16/05ISR Number: 4589265-3Report Type:Expedited (15-DaCompany Report #SUSI-2005-00075 Age: Gender: I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Mania	Literature Health Professional	Adderall (Dextroamphetamine Sulfate, Dextromphetamine			
				Saccharate, Divalproex Sodium	PS		
				(Valproate Semisodium)	С		
Date:02/16/0	ISTSR Number	·: 4589267-7Report Type:Expe	dited (15-DaCompany Re	eport #SUSI-2005-00013			
	Gender:Fema		areca (15 Dacompany ne	-pore "BODY 2000 00013			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other SEE IMAGE	Duración	Electrocardiogram Qt	Health	Adderall Xr	PS		
		Corrected Interval Prolonged Sinus Tachycardia	Professional				
		-					
	5ISR Number Gender:Male	: 4589270-7Report Type:Expe I/FU:I	dited (15-DaCompany Re	eport #SUSI-2005-00072			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P		Circulatory Collapse Drug Ineffective Loss Of Consciousness Movement Disorder Tic	Consumer	Adderall (Dextroamphetamine Sulfate, Dextroamphetamine Saccharate,	PS		
SEE IMAGE		Tourette'S Disorder					
4		ICALCOUC D DIDOLACI					

Date:02/16/05ISR Number: 4589349-XReport Type:Direct Age:8 YR Gender:Male I/FU:I Company Report #CTU 240515

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalizat	ion -	Attention		Adderall	PS	Shire	
1 PILL TO 2							
Initial or F	rolonged	Deficit/Hyperactivity					
PILLS A DAY							
Disability		Disorder					
-15 MG [ ON							
Required AND OFF]		Hyperventilation					
Intervention		Loss Of Consciousness					
Prevent Perm		Movement Disorder					
Impairment/I		Tic					
1Fa11		Tourette'S Disorder					
		: 4585027-1Report Type:Periodi	.c Company	Report #US-GLAXOSMITHKL	INE-A05366	67A	
Age:	Gender:	I/FU:F					
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Hypnagogic Hallucination		Wellbutrin Xl	PS	Glaxosmithkline	ORAL
				Adderall	SS		
UNKNOWN							

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:02/17/05ISR Number: 4586730-XReport Type:Direct Company Report #CTU 240634 Age: Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Agitation Adderall (Generics) PS 0.20 MG BID -Drug Ineffective QID 7 YR Pharmaceutical Product Buspirone (Generic Complaint (30 Mg Bid) 4 Yrs) SS 10 MG TID -QID Date:02/17/05ISR Number: 4586854-7Report Type:Direct Company Report #CTU 240696 Age:14 YR Gender:Male I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Life-Threatening Abnormal Behaviour Adderall Xr 20mg Shire Hospitalization -Agitation PS Shire ORAL 20 MG PER Initial or Prolonged Confusional State DAY ORAL Delirium Drug Effect Prolonged Drug Toxicity Heart Rate Increased Influenza Insomnia Paranoia Pharmaceutical Product Complaint Thinking Abnormal Date:02/17/05ISR Number: 4589221-5Report Type:Direct Company Report #CTU 240732 Age:10 YR Gender:Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Hospitalization -Abnormal Behaviour Adderall Xr 15 Mg

Capsule Sshi

Initial or Prolonged

Aggression

1 01 2 0 0 0 0 0 0	Amnesia		Ndc#54092038501	PS		ORAL
1 CAPSULE IN	Feeling Hot					
EARLY MORNING	reciting not					
	Overdose					
ORAL						
	er: 4587202-9Report Type:Expedite	d (15-DaCompany Repo	ort #US-GLAXOSMITHKLIN	IE-A05187	64A	
Age:45 YR Gender:Fer	nale I/FU:F					
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Disability 5MG See	Cardiomegaly		Dexedrine	PS	Glaxosmithkline	ORAL
	Chest Discomfort					
dosage text						
	Chest Pain		Adderall	SS		
	Cough		Meridia	SS		
	Dilatation Ventricular		Paxil Cr	С	Glaxosmithkline	
25MG Per day						
	Dyspnoea Exertional		Ciprofloxacin	С		
	Fatigue		Lexapro	С		
	Insomnia		Vicodin	С		
	Palpitations		Effexor	С		
	Pericardial Effusion		Diazepam	С		
	Pulmonary Hypertension					
	Pyrexia					
	Respiratory Distress					
	Tricuspid Valve					
	Incompetence					

			e Event Reporting Syste Of Information (FOI) Re		RS)	
				-		
Date:02/18/05ISR Number Age:57 YR Gender:Fema	r: 4590631-0Report Type:Direct ale I/FU:I	Company Repo	rt #CTU 240769			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Disability 2 TIMES A DAY	Dyspnoea		Adderall	PS	Abriika	
	Pharmaceutical Product Complaint Urticaria					
Date:02/22/05ISR Numbe Age:5 YR Gender:Male	r: 4591018-7Report Type:Direct e I/FU:I	Company Repo	rt #CTU 241019			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Chest Pain Heart Rate Increased		Adderall Xr 10 Mg Capsules	PS		ORAL
1 CAPSULE 1 DAILY ORAL	Palpitations					
Date:02/23/05ISR Number Age: Gender:Fema	r: 4594894-7Report Type:Expedi ale I/FU:I	ted (15-DaCompany Repo	rt #SUS1-2005-00095			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Hallucination	Foreign Health Professional Other	Adderall Xr (Dextroamphetamne Saccharate, Amphetamine Sulfate,			
			Amphetamine	PS		
Date:02/24/05ISR Number Age:44 YR Gender:Fema	r: 4595899-2Report Type:Direct ale I/FU:I	Company Repo	rt #CTU 241294			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Required ONCE A DAY	Cerebrovascular Accident		Adderall	PS		ORAL

Interventio ORAL	n to	Fall						
Prevent Per Impairment/		Somnolence			Lexapro	С		
Date:02/24/ Age:	05ISR Number: Gender:Male	: 4595905-5Report Type:Direct I/FU:I		Company Report	t #CTU 241296			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Death		No Adverse Drug Effect			Adderall Xr 30 Mg	PS		
		: 4597573-5Report Type:Direct		Company Report	t #CTU 241614			
2	Gender:Male					_		
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Hospitaliza ONCE DAILY		Abnormal Behaviour			Paxil	PS		ORAL
Initial or ORAL	Prolonged	Affective Disorder						
ONCE DAILY		Aggression			Adderall	SS		ORAL
ORAL		Bipolar Disorder						
ORAL		Educational Problem Mania			Concerta	SS		

			e Event Reporting Syste Of Information (FOI) Re		
Date:02/28/05ISR Number Age:7.5 YR Gender:Male	: 4597574-7Report Type:Direct I/FU:I	Company Repor		-	
Outcome Dose Duration Death	PT Arrhythmia Bicuspid Aortic Valve	Report Source	Product Adderall	Role Manufacturer PS	Route
Date:02/28/05ISR Number Age: Gender:Male	: 4597597-8Report Type:Direct I/FU:I	Company Repor	t #CTU 241600		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Death ONE DAY ORAL	Eye Haemorrhage Sudden Death		Adderall Rx	PS	ORAL
Date:02/28/05ISR Number Age:54 YR Gender:Male	: 4597618-2Report Type:Direct I/FU:I	Company Repor	t #CTU 241635		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Life-Threatening 60 MG ONCE	Cardiomyopathy		Adderall	PS	
Hospitalization - DAILY 5 YR	Endocardial				
Initial or Prolonged Disability	Fibroelastosis Hypokinesia Ventricular Dysfunction				
Date:03/01/05ISR Number Age:61 YR Gender:Male	: 4598135-6Report Type:Direct I/FU:I	Company Repor	rt #CTU 241673		
Outcome Dose Duration	РТ	Report Source	Product	Role Manufacturer	Route
Hospitalization - 40 MG DAILY	Atrial Fibrillation		Adderall 40 Mg Daily	PS	
Initial or Prolonged 40 MG DAILY	Dizziness		Adderall	SS	
	Dyspnoea Exertional Fatigue		Indomethacin Sertraline	C C	

Sleep Apnoea Syndrome

Date:03/03/05ISR Number: 4599587-8Report Type:Expedited (15-DaCompany Report #SUSI-2005-00120 Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged	Accident Balance Disorder Brain Oedema Cerebral Haemorrhage	Health Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine			
	Concussion		Saccharate,	PS		
30 MG,						
1	Head Injury					
1X/DAY:QD				~		
	Hypoaesthesia Loss Of Consciousness		Focculine	С		
	Loss Of Consciousness Skull Fractured Base					
Date:03/03/05ISR Numb Age:11 YR Gender:Ma	per: 4599589-1Report Type:Exped ale I/FU:I	ited (15-DaCompany R	eport #SUSI-2005-00116			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration	1	-				
Death	Cardio-Respiratory Arrest Coma Fatigue	Other	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine			
15 MG,			Saccharate,	PS		
22 AUX 2005 10.24 AM	a.					

Freedom Of Information (FOI) Report

						<b>/</b>
1X/DAY:QD			Wellbutrin-Slow Release (Bupropion			
300 MG/DAY;			Hydrochloride)	SS		ļ
SEE IMAGE			Strattera			ļ
			(Atomoxetine Hydrochloride)	SS		
Date:03/03/05ISR Number Age:11 YR Gender:Male						
Outcome Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Life-Threatening	Supraventricular Tachycardia	Health Professional	Adderall Xr(Dextroamphetamine Sulfate, Dextroamphetamine Saccharate,	PS		
10 MG,			Saccharace,	РЪ		
1X/DAY; QD						
Date:03/03/05ISR Number Age:39 YR Gender:Male	r: 4600229-3Report Type:Direct e I/FU:I	Company Repor	rt #CTU 241984			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Required Intervention to 1 DAILY	Blood Pressure Increased Disorientation		Adderall Xr 30 Mg.	PS		ORAL
Prevent Permanent ORAL Impairment/Damage	Dizziness					

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
	Duration						
Other		Fatigue	Foreign	Adderall Xr			ļ
		Impaired Work Ability	Consumer	(Dextroamphetamine			
		Prescribed Overdose	Other	Sulfate,			ļ
l		Renal Failure		Dextroamphetamine			Į
				Saccharate,	PS		ORAL
45 MG/DAY,							
ORAL							<b>/</b>
1				Cortone (Cortisone			Į
				Acetate)	С		Į
l				Wellbutrin			ļ
l				(Bupropion			ļ
l				Hydrochloride)	С		ļ
	SISR Number: Gender:Male	: 4601058-7Report Type:Direct I/FU:I	Company Repo:	rt #CTU 242211			
Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose I	Duration						
Required		Mania		Generic Adderall			
Intervention t 1 1/2 TAB	to	Pharmaceutical Product		10mg	PS		
Prevent Perman	.nent	Complaint					
AM							ļ
Impairment/Dar	mage	Suicidal Ideation					

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:03/08/05ISR Number: 4603756-8Report Type:Direct Company Report #CTU 242281 Gender:Female Age: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Other Chest Pain Adderall Xr PS 10 MG DAILY Headache FOR 1 WEEK, Heart Rate Increased THEN 20 MG Palpitations ONCE DAILY Weight Decreased Remeron С Zoloft С С Topamax Date:03/09/05ISR Number: 4604045-8Report Type:Direct Company Report #CTU 242420 Age:51 YR Gender:Male I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Drug Ineffective Adderall (Generic) ORAL Other PS 15 MG TID PO Pharmaceutical Product Complaint Date:03/11/05ISR Number: 4679214-1Report Type:Direct Company Report #CTU 242675 Age:5 YR Gender:Male I/FU:I  $\mathbf{PT}$ Report Source Role Manufacturer Outcome Product Route Dose Duration Drug Ineffective Adderall (Generic) Other PS 15 MG BID (AT Therapeutic Response TIME OF EVENT Unexpected With Drug DOSE WAS 10 Substitution MG AM & 5 MG AFT.

Adderall

С

				Strattera Seroquel Klonopin Abilify	C C C C C C		
	)5ISR Number Gender:Male	: 4610960-1Report Type:Direct I/FU:I	Company Repor	rt #CTU 243289			
Outcome Dose	Duration	PT	Report Source	Product	Role M	Manufacturer	Route
Dose Other 10 MG ONCE	Duracion	Allergy To Animal		Adderall	PS		ORAL
		Bundle Branch Block					
DAILY ORALLY	7	Cough		Adderall	SS		ORAL
20 MG ONCE		Drug Effect Decreased					
DAILY ORALLY	7			Flintstones Chewable Multivitamins	С		
	)5ISR Number Gender:Male	: 4614256-3Report Type:Expedit I/FU:I	ced (15-DaCompany Repor	t #SUS1-2005-00185			

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other 20 MG,		Arteriospasm Coronary Chest Discomfort Nausea Palpitations	Consumer	Adderall(Dextroamphe tamine Sulfate, Dextroamphetamine, Saccharate, Amphetamine Sulfate,	PS		
1X/DAY; QD				Aspirin Migraene (Acetylsalicylic			

Freedom Of Information (FOI) Report

Acid) C Niacin (Nicotinic Acid) C

Date:03/17/05ISR Number: 4611579-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0544527A Age:32 YR Gender:Female I/FU:F

Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other 27 DAY		Confusional State			Wellbutrin	PS	Glaxosmithkline	ORAL
		Dysphemia Grand Mal Convulsion Overdose Postictal State Sleep Disorder Tonic Clonic Movements			Adderall Cold Medication	SS SS		
	05ISR Number Gender:Fema	: 4614975-9Report Type:Direct le I/FU:I		Company Repor	t #CTU 243754			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other ONE BD		Convulsion Pharmaceutical Product			Adderall 30 (Generic)	PS		
		Complaint						
Date:03/18/0 Age:	05ISR Number Gender:Fema	: 4619565-XReport Type:Direct le I/FU:I		Company Repor	t #CTU 243618			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Hospitalizat PO		Feeling Abnormal			Adderal	PS		
Initial or D	Prolonged	Heart Rate Irregular Paraesthesia			Stool Softeners Klonopin Depakote	C C C		

Date:03/21/05ISR Number Age:10 YR Gender:Male	: 4616250-5Report Type:Expedi e I/FU:I	ted (15-DaCompany Repo	rt #SUS1-2005-00189			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Stevens-Johnson Syndrome	Health Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine			
10 MG,			Saccharate,	PS		ORAL
1X/DAY:QD,						
ORAL			Amfetamin Asp W/Amfet Sul/Dexam Sa/Dexam Sul (Dexamfetamine Sulfate, Amfetamine	С		
Date:03/21/05ISR Number Age:10 YR Gender:Male	: 4616251-7Report Type:Expedi e I/FU:I	ted (15-DaCompany Repo	rt #SUS1-2005-00138			
Outcome Life-Threatening Hospitalization - Initial or Prolonged						
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Required							
Intervention to							
Prevent Permanent Dose Durat	PT		Report Source	Product	Role	Manufacturer	Route
Impairment/Damage	Abdomina Agitatio Chest Pa	n in nal State	Health Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine Saccharate,	PS		ORAL
37-20 MG							
TABLETS, ORAL	Fear						
	Heart Ra Incohere: Insomnia Intentio Mydriasi Nausea Psychoti Pupillar Suicide	te Increased te Irregular nt nal Misuse s c Disorder y Reflex Impaire Attempt		Report #SUS1-2005-00190			
Outcome	PT .		Report Source	Product	Role	Manufacturer	Route
Dose Durat Hospitalization - Initial or Prolong	Drooling		Health Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine Saccharate,	PS		
Age:7 YR Gender Outcome		-0Report Type:Ex FU:I	pedited (15-DaCompany Report Source	Report #SUS1-2005-00168 Product	Role	Manufacturer	Route
Dose Durat	ion Angina P			Adderall(Dextroamp			

	Saccharate, Amphetamine Sulfate,	PS	ORAL
1X/DAY: QD,			
	Adderall Xr (Dextroamphetamine Aspartate) Tablet	SS	ORAL
1X/DAY: QD,			
ORAL			

Date:03/21/05ISR Number: 4616309-2Report Type:Expedited (15-DaCompany Report #SUS1-2005-00092 Age:49 YR Gender:Female I/FU:F

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Condition Aggravated Crohn'S Disease	Professional	Adderall(Dextroamphe tamine Sulfate, Dextroamphetamine Saccharate, Amphetamine Sulfate,	PS		
10 MG,							

1X/DAY: QD

Freedom Of Information (FOI) Report

Strattera	
(Atomoxetine	
Hydrochloride)	С
Elavil	
(Amitriptyline	
Hydrochloride)	С
Aricept (Donepezil	
Hydrochloride)	С
Wellbutrin	
(Bupropion	
Hydrochloride)	С
Prozac (Fluoxetine	
Hydrochloride)	С

Date:03/21/05ISR Number: 4616311-0Report Type:Expedited (15-DaCompany Report #SUS1-2005-00167 Age:14 YR Gender:Female I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Durución	Anorexia Aortic Valve Incompetence Autonomic Nervous System Imbalance	Consumer	Adderall Xr(Dextroamphetamine Sulfate, Dextroamphetamine	DQ		ODAL
SEE IMAGE,		Cough		Saccharate,	PS		ORAL
SEE IMAGE,		Dizziness					
ORAL							
		Heart Rate Decreased Loss Of Consciousness Orthostatic Hypotension Paraesthesia Syncope Vasovagal Weight Decreased Wheezing		Proamatine (Midodrine Hydrochloride) Prevacid (Lansoprazole) Florinef (Fludrocortisone Acetate) Bactrim (Sulfamethoxazole,	с с с		
				(Sullamethoxazole, Trimethoprim)	С		

Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose	Duration							
Other		Anorexia			Adderall Xr	PS	Shire Us Inc	ORAL
15MG DAY ORA	AL .							
		Blood Pressure Increased Headache						
		Stomach Discomfort Weight Decreased						
	)5ISR Number Gender:Male	: 4620153-XReport Type:Direct I/FU:I		Company Repor	rt #CTU 243916			
Outcome		PT	Report	Source	Product	Role	Manufacturer	Route
Dose	Duration							
		Anorexia Blood Pressure Increased Headache Somnolence Stomach Discomfort Weight Decreased			Adderall Xr	ΡS		

		FDA - Advers	e Event Reporting Syst	em (AEF	RS)	
		Freedom	Of Information (FOI) R	eport		
Date:03/24/05ISR Number Age:58 YR Gender:Male	r: 4621345-6Report Type:Direct I/FU:I	Company Repo	ort #CTU 244191			
Outcome Dose Duration Hospitalization -	PT Bundle Branch Block Left	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Evencie Branch Block Left Cyanosis Dyspnoea Exercise Capacity Decreased Fatigue Nasopharyngitis Oedema Peripheral		Adderall Unknown	PS		
Date:03/29/05ISR Number Age:16 YR Gender:Male	: 4622705-XReport Type:Direct I/FU:I	Company Repo	ort #CTU 244588			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Life-Threatening	Coma		Adderall Xr 10mg?			
Hospitalization - 1 TAB DAILY	Depressed Level Of		Unk	PS		ORAL
Initial or Prolonged ORAL	Consciousness					
Required	Dyspnoea					
Intervention to	Hallucination					
Prevent Permanent Impairment/Damage	Respiratory Arrest Salivary Hypersecretion Tourette'S Disorder					
	Unresponsive To Verbal Stimuli					
Date:03/29/05ISR Number Age:74 YR Gender:Fema	: 4622710-3Report Type:Direct le I/FU:I	Company Repo	ort #CTU 244585			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threatening Disability Other	Anxiety Blood Pressure Increased General Physical Health Deterioration Tic Tremor		Adderall	PS		

Visual Acuity Reduced

Date:03/31/05ISR Number: 4627211-4Report Type:Expedited (15-DaCompany Report #SUS1-2005-00218 Age:10 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Sudden Death	Health Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine Saccharate,	PS		
Date:03/31 Age:29 YR	/05ISR Numbe: Gender:Male	r: 4627212-6Report Type:Exj e I/FU:I	pedited (15-DaCompany Re	eport #SUS1-2005-00209			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threa Hospitaliza Initial or	tening ation -	Mental Disorder Sexual Dysfunction Stress	Consumer	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine			
22-Aug-200							

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Freedom Of Information (FOI) Report

Saccharate,	PS
Adderall Xr	
(Dextroamphetamine	
Sulfate,	
Dextroamphetamine	
Saccharate,	SS

								ł
Date:04/01/0 Age:43 YR		: 4626898-XReport Type:Direct I/FU:I		Company Report	ε #CTU 245055			
Outcome Dose	Duration	PT	Report S	Source	Product	Role	Manufacturer	Route
Dose Death 10 MG PO QD	DULALION	Subarachnoid Haemorrhage			Adderall	PS		ORAL
75 MG PO QD					Effexor	SS		ORAL
Date:04/04/0 Age:21 YR		: 4629238-5Report Type:Direct I/FU:I		Company Report	t #CTU 245126			
Outcome		PT	Report S	Source	Product	Role	Manufacturer	Route
Dose Disability		Abnormal Behaviour			Adderal 10 Mg	PS		ORAL
10 MG PO TID Other 30 MG XR		Antisocial Behaviour			Adderal Xr 30 Mg	SS		
DAILY		Depression						I
ЛАТТТ		Disturbance In Attention Educational Problem Loss Of Employment Suicidal Ideation						
Date:04/05/0 Age:10 YR		: 4627995-5Report Type:Direct I/FU:I		Company Report	t #CTU 245338			
Outcome Dose	Duration	PT	Report S	Source	Product	Role	Manufacturer	Route
Life-Threate 1 QD		Stevens-Johnson Syndrome			Adderall Xr 10 Mg	PS		
		Toxic Epidermal Necrolysis						

Date:04/06/05ISR Number Age: Gender:Fema	r: 4631053-3Report Type:Direct ale I/FU:I	Company Repo	rt #CTU 245465		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Other PO X 3D	Drug Ineffective		Adderall (Generic)	PS	
PO	Pharmaceutical Product		Adderall Xr	SS	ORAL
	Complaint				
Date:04/07/05ISR Number Age:12 YR Gender:Male	r: 4631143-5Report Type:Direct e I/FU:I	Company Repo	rt #CTU 245555		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Life-Threatening 1 DAILY	Hallucination, Auditory		Adderall Xr 30	PS	ORAL
Hospitalization - ORAL	Hallucination, Visual				
Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Suicide Attempt				

Freedom Of Information (FOI) Report

Date:04/08/05ISR Number: 4630520-6Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0518764A Age:45 YR Gender:Female I/FU:F

Outcome Dose I	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose I Disability 5MG See	Duration	Cardiomegaly		Dexedrine	PS	Glaxosmithkline	ORAL
		Chest Discomfort					
dosage text							
		Chest Pain		Adderall	SS		
		Cough		Meridia	SS		
OFMO Dow dow		Dilatation Ventricular		Paxil Cr	С	Glaxosmithkline	
25MG Per day		Dyspnoea Exertional		Ciprofloxacin	С		
		Fatigue		Lexapro	C		
		Insomnia		Vicodin	C		
l		Palpitations		Effexor	C		
		Pericardial Effusion		Diazepam	C		
		Pulmonary Hypertension		Drazepam	C		
		Pyrexia					
		Respiratory Distress					
		Tricuspid Valve					
		Incompetence					
	ISR Number ender:Fema	: 4634344-5Report Type:Expe le I/FU:I	dited (15-DaCompany Re	eport #SUS1-2005-00234			
Outcome Dose I	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death		Sudden Cardiac Death	Health Professional Other	Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
20 MG IN				Deneroampriceamirie	10		
A.M.; 10 MG							
IN P.M.							
				Strattera			
				(Atomoxetine			

С

Hydrochloride)

Age:12 YR Ge	ender:Femal	: 4638163-5Report Type:Expedi le I/FU:F	.ted (15-DaCompany Re	port #SUS1-2005-00234			
Outcome Dose I	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death 20 MG IN A.M;		Heart Rate Increased	Health	Adderall	PS		ORAL
10 MG IN P.M.		Sudden Cardiac Death	Professional				
				Strattera (Atomoxetine Hydrochloride)	С		
	ISR Number Gender:Male	: 4638164-7Report Type:Expedi I/FU:I	ited (15-DaCompany Re	port #SUS1-2005-00269			
		PT	Report Source	Product	Role	Manufacturer	Route
Dose I	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose I Life-Threaten: 10 MG,		PT Affect Lability	Report Source Health	Product Adderall Xr	Role PS	Manufacturer	Route ORAL
Life-Threaten:	ning					Manufacturer	
Life-Threaten: 10 MG, Hospitalizatio	.on -	Affect Lability	Health			Manufacturer	

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:04/15/05ISR Number: 4639096-0Report Type:Direct Company Report #CTU 246248 Age: Gender: I/FU:I Outcome PTReport Source Product Role Manufacturer Route Duration Dose Drug Ineffective Ritalin PSDrug Intolerance SS Strattera Adderall SS Date:04/18/05ISR Number: 4638186-6Report Type:Expedited (15-DaCompany Report #SUSI-2005-00270 Age: Gender:Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Drug Abuser Health Adderall Xr Death PS20 MG, 1 Professional X/DAY:QD, UNK Cocaine(Cocaine) SS Heroin (Diamorphine) SS Celexa (Citalopram Hydrobromide) С Date:04/18/05ISR Number: 4638190-8Report Type:Expedited (15-DaCompany Report #SUSI-2005-00271 Gender:Female Age:17 YR I/FU:I Role Manufacturer Outcome PTReport Source Product Route Dose Duration Blood Pressure Increased Health Adderall Xr PS Death 60 MG, Cardiomegaly Professional 1X/DAY;QD, Off Label Use UNK Prescribed Overdose Glucopahge Sudden Cardiac Death (Metformin) С Treatment Noncompliance Ventricular Hypertrophy Weight Increased

Date:04/19/05ISR Num Age:17 YR Gender:Fo	ber: 4641023-7Report Type:Direc emale I/FU:I	ct Company Re	eport #CTU 246564		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Other	Anxiety Attention		Adderall 20 Mg Q Am Po	PS	ORAL
20 mg q am po	Deficit/Hyperactivity Disorder Disturbance In Attention Drug Ineffective Pharmaceutical Product Complaint Therapeutic Response Unexpected With Drug Substitution		Zoloft Mircette	C C	
Date:04/22/05ISR Num Age:17 YR Gender:Fo	ber: 4643357-9Report Type:Expec emale I/FU:F	lited (15-DaCompany Re	eport #SUS1-2005-00271		
Outcome Death	PT Apathy Blood Pressure Increased Cardio-Respiratory Arrest Cardiomegaly Off Label Use				

Freedom Of Information (FOI) Report

_		Prescribed Overdose Sudden Cardiac Death Treatment Noncompliance	Report Source	Product	Role	Manufacturer	Route
Dose		Ventricular Hypertrophy Weight Increased	Health Professional	Adderall Xr(Dextroamphetamine Sulfate,Dextroamphet amine			
60 MG,				Saccharate,Amphetami	PS		
1X/DAY:QD							
				Glucophage (Metformin)	С		
	5ISR Number: Gender:Femal	: 4644492-1Report Type:Direct le I/FU:I	Company Repor	rt #CTU 247050			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose		Somnolence		Adderall Xr 10mg	PS		
	5ISR Number: Gender:Male	: 4644584-7Report Type:Direct I/FU:I	Company Repor	rt #CTU 247057			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
		Agonal Rhythm		Adderall 15mg Xr	PS		ORAL
ONE PO QAM		Arrhythmia Cardiac Arrest Cardio-Respiratory Arrest Circulatory Collapse Pulse Absent					
	5ISR Number: Gender:Male	: 4644722-6Report Type:Expedite I/FU:I	ed (15-DaCompany Repor	:t #PHEH2005US04677			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Life-Threate		Abnormal Behaviour		Lamisil	PS	Novartis Sector:	

Hospitalization	- Depression				Pharma	ORAL
250 mg, QD Initial or Prolo 20 mg, QD	nged Suicidal Ideation	Suicidal Ideation		SS		ORAL
	Suicide Attempt					
	R Number: 4648776-2Report der:Female I/FU:F	Type:Expedited (15-DaCompany	Report #SUSI-2005-00234			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Dur Death	ration Heart Rate Increa Sudden Cardiac De		Adderall (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
20 MG IN			Dereroumpneeumrne	тъ		
A.M.; 10 MG						
IN P.M.						
			Strattera (Atomoxetine Hydrochloride)	С		

Freedom Of Information (FOI) Report

Date:04/27/05ISR Number: 4648812-3Report Type:Expedited (15-DaCompany Report #SUSI-2005-00279 Age:27 YR Gender:Male I/FU:I

Angina Pectoris	~				
Coronary Arterial Stent Insertion Nausea	Consumer Health Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine Saccharate,	PS		
		Saccharace,	15		
		Warfarin Sodium (Warfarin Sodium) Plavix (Clopidogrel Sulfate) Acetylsalicylic Acid (Acetylsalicylic Acid) Fish Oil (Fish Oil) Coenzyme Q10 (Ubidecarenone) Simvastatin (Simvastatin) Allegra (Fexofenadine Hydrochloride) Klonopin (Clonazepam) Altace (Ramipril) Toprol Xl (Metoprolol Succinate)	с с с с с с с с с с с с с с с с с с с		
		(Lansprazole) Ritalin (Methylphenidate	C		
			Warfarin Sodium (Warfarin Sodium) Plavix (Clopidogrel Sulfate) Acetylsalicylic Acid (Acetylsalicylic Acid) Fish Oil (Fish Oil) Coenzyme Q10 (Ubidecarenone) Simvastatin (Simvastatin) Allegra (Fexofenadine Hydrochloride) Klonopin (Clonazepam) Altace (Ramipril) Toprol Xl (Metoprolol Succinate) Prevacid (Lansprazole) Ritalin	Warfarin Sodium (Warfarin Sodium) C Plavix (Clopidogrel Sulfate) C Acetylsalicylic Acid (Acetylsalicylic Acid) C Fish Oil (Fish Oil) C Coenzyme Q10 (Ubidecarenone) C Simvastatin C (Simvastatin) C Allegra ( Fexofenadine Hydrochloride) C Klonopin (Clonazepam) C Altace (Ramipril) C Toprol X1 (Metoprolol Succinate) C Prevacid (Lansprazole) C Ritalin (Methylphenidate	Warfarin Sodium (Warfarin Sodium) C Plavix (Clopidogrel Sulfate) C Acetylsalicylic Acid (Acetylsalicylic Acid) Acid) C Fish Oil (Fish Oil) C Coenzyme Ql0 (Ubidecarenone) C Simvastatin (Simvastatin) C Allegra (Fexofenadine Hydrochloride) C Klonopin (Clonazepam) C Altace (Ramipril) C Toprol Xl (Metoprolol Succinate) C Prevacid (Lansprazole) C Ritalin (Methylphenidate

Date:04/27/05ISR Number: 4648816-0Report Type:Expedited (15-DaCompany Report #SUSI-2005-00308 Age: Gender:Unknown I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Dizziness	Health	Adderall Xr			
		Syncope	Professional	(Dextroamphetamine			

Sulfate, Dextroamphetamine Saccharate, PS Zyrtec (Cetirizine Hydrochloride) C Allegra (Fexofenadine Hydrochloride) C

Date:04/27/05ISR Number: 4648923-2Report Type:Expedited (15-DaCompany Report #SUS1-2005-00134 Age:11 YR Gender:Male I/FU:F

Outcome PT Life-Threatening Abdominal Pain Upper Electrocardiogram P Wave Abnormal Electrocardiogram Qrs Complex Shortened

Freedom Of Information (FOI) Report

		Headache Pallor					
Dose	Duration	Pharyngeal Oedema	Report Source	Product	Role	Manufacturer	Route
		Supraventricular Tachycardia Ventricular Extrasystoles	Health Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine			
10 MG,				Saccharate,	PS		
1X/DAY: QD					~		
				Motrin (Ibuprofen)	С		
	5ISR Number: Gender:Male	: 4649414-5Report Type:Direct I/FU:I	Company Repor	t #CTU 247335			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
BID PO	Durución	Pharmaceutical Product		Adderall 20mg	PS		ORAL
		Complaint					
	5ISR Number Gender:Male	: 4649417-0Report Type:Direct I/FU:I	Company Repor	t #CTU 247390			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
DORE	Duración	Disturbance In Attention Drug Ineffective Pharmaceutical Product Complaint Psychomotor Hyperactivity		Adderall	PS		
Date:04/28/0 Age:10 YR		: 4649419-4Report Type:Direct I/FU:I	Company Repor	t #CTU 247397			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat		Blister		Adderall Xr 10mg			

Initial or Prolonged 10 MG QAM PO	Malaise		(Shire)	PS	Shire	ORAL
Required Intervention to Prevent Permanent Impairment/Damage	Oral Mucosal Exfoliation Pyrexia Rash Erythematous Rash Generalised Rash Macular		Amphetamine Salts	С		
Date:05/03/05ISR Numbe Age:20 YR Gender:Fem	er: 4653127-3Report Type:Exped male I/FU:F	lited (15-DaCompany Rep	ort #SUS1-2005-00270			
Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death Duration	Drug Abuser Sudden Death	Health Professional	Adderall Xr (Dextroamphetamine Sulfate,Dextroamphet amine Saccharate,Amphetami	PS		
20-30 MG IN						
MORNING, UNK				22		
			Cocaine(Cocaine) Heroin(Diamorphine) Celexa (Citalopram	SS SS		
			Hydrobromide)	С		

Freedom Of Information (FOI) Report

Date:05/03/05ISR Number: 4653131-5Report Type:Expedited (15-DaCompany Report #SUS1-2005-00189 Age:10 YR Gender:Male I/FU:F

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration Hospitalization - Initial or Prolonged Other	Anaemia Conjunctivitis Depression Gallbladder Disorder Hydronephrosis	Health Professional	Adderall Xr (Dextroamphetamine Sulfate,Dextroamphet amine Saccharate,Amphetami	PS		ORAL
10 MG, Q AM,			Daconarace, mapricea	10		010112
ORAL	Leukopenia					
	Mental Status Changes Platelet Count Decreased Pleural Effusion Pneumonia Mycoplasmal Post-Traumatic Stress Disorder Renal Failure Acute Rocky Mountain Spotted Fever Sepsis Stevens-Johnson Syndrome Stridor Tachycardia Toxic Epidermal Necrolysis		Amphetmaine Salts	С		
Date:05/03/05ISR Number Age:10 YR Gender:Male	r: 4653134-0Report Type:Expedi e I/FU:F	ted (15-DaCompany Repo	rt #SUS1-2005-00269			
-	PT	Demonst Courses	Product	Dele	Manufacturer	Deute
Outcome Dose Duration	PT	Report Source	Product	коте	Manulacturer	Route
Life-Threatening Hospitalization - Initial or Prolonged	Affect Lability Stevens-Johnson Syndrome Toxic Epidermal Necrolysis	Health Professional	Adderall Xr(Dextroamphetamine Sulfate,Dextroamphet amine Saccharate,Amphetami	פק		ORAL
10 MG,			bacenarace, mapriceami	10		Olum
1 V / J V · OD						

1X/DAY:QD,

ORAL

tamine Sulfate, Dextroamphetamine Saccharate, Amphetamine Sulfate, C

Date:05/03/05ISR Number: 4653369-7Report Type:Expedited (15-DaCompany Report #SUS1-2005-00339 Age:10 YR Gender:Male I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Dyspnoea	Foreign	Adderall Xr			
		Throat Tightness	Other	(Dextroamphetamine			
		Visual Disturbance		Sulfate,			
				Dextroamphetamine			
				Saccharate,	PS		ORAL
30 MG, ONED	)						

DOSE, ORAL 1 DAY

Freedom Of Information (FOI) Report

Date:05/03/05ISR Number: 4653370-3Report Type:Expedited (15-DaCompany Report #SUS1-2005-00341 Age:36 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration		-				
Other		Anxiety	Foreign	Adderall Xr			
		Exophthalmos	Other	(Dextroamphetamine			
		Prescribed Overdose		Sulfate,			
		Rash		Dextroamphetamine			
		Swollen Tongue		Saccharate,	PS		ORAL
140 MG DAII	LY,						
		Throat Tightness					
ORAL	365 DAY	Y					
				Trazodone			
				(Trazodone)	С		
		r: 4653373-9Report Type:Ex	pedited (15-DaCompany Re	eport #SUS1-2005-00337			
Date:05/03, Age:29 YR Outcome	/05ISR Number Gender:Fema		pedited (15-DaCompany Re Report Source	eport #SUS1-2005-00337 Product	Role	Manufacturer	Route
Age:29 YR		ale I/FU:I	Report Source		Role	Manufacturer	Route
Age:29 YR Outcome	Gender:Fema	ale I/FU:I PT Erythema	Report Source Foreign	Product Adderall Xr	Role	Manufacturer	Route
Age:29 YR Outcome Dose	Gender:Fema	PT	Report Source	Product Adderall Xr (Dextroamphetamine	Role	Manufacturer	Route
Age:29 YR Outcome Dose	Gender:Fema	ale I/FU:I PT Erythema	Report Source Foreign	Product Adderall Xr (Dextroamphetamine Sulfate,	Role	Manufacturer	Route
Age:29 YR Outcome Dose	Gender:Fema	ale I/FU:I PT Erythema	Report Source Foreign	Product Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine		Manufacturer	
Age:29 YR Outcome Dose Other	Gender:Fema	ale I/FU:I PT Erythema	Report Source Foreign	Product Adderall Xr (Dextroamphetamine Sulfate,	Role PS	Manufacturer	Route ORAL
Age:29 YR Outcome Dose	Gender:Fema	ale I/FU:I PT Erythema	Report Source Foreign	Product Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine		Manufacturer	
Age:29 YR Outcome Dose Other	Gender:Fema	ale I/FU:I PT Erythema Urticaria	Report Source Foreign	Product Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine		Manufacturer	
Age:29 YR Outcome Dose Other 20 MG DAILY	Gender:Fema Duration	ale I/FU:I PT Erythema Urticaria	Report Source Foreign	Product Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine		Manufacturer	

Acetaminophen	С
Clonazepam	
(Clonazepam)	С
Epival (Valproate	
Semisodium)	С
Salbutamol	
(Salbutamol)	С
Venlafaxine	
(Venlafaxine)	С
Xenical (Orlistat)	С
Zopiclone	
(Zopiclone)	С
Seroquel (Quetiapine	2
Fumarate)	С

Date:05/05/0 Age:	)5ISR Number: Gender:Male	: 4654503-5Report Type:Direc I/FU:I	t	Company	Repor	t #CTU 247837				
Outcome Dose	Duration	PT	Report	Source		Product	Role	Manufacturer	F	Route
BID PO		Drug Ineffective				Adderall 20 Mg	PS		(	ORAL
		Pharmaceutical Product Complaint Therapeutic Response Unexpected With Drug Substitution								
	)5ISR Number: Gender:Male	: 4662642-8Report Type:Direc I/FU:I	t	Company	Repor	t #CTU 248466				
Outcome										
Life-Threate Hospitalizat										
Initial or D										
Required Intervention	n to									
Prevent Perr	nanent									
22-Aug-2005 Page: 192	10:34 AM									

## Freedom Of Information (FOI) Report

Impairment/Damage

Dogo	Duration	РТ	Report	Source	Product		Role	Manufacturer	Route
		Acute Myocardial Infarction			Adderal-Xr Shire	20mg	PS	Shire	ORAL
20MG BID ORAL		Arteriospasm Coronary							
		Back Pain Coronary Artery Disease Headache Musculoskeletal Stiffness Pyrexia			Effexor-Xr Topomax Celexa		C C C		
Date:05/16/05 Age:46 YR G		: 4664001-0Report Type:Direct le I/FU:I		Company Report	t #CTU 248653				
Outcome		PT	Report	Source	Product		Role	Manufacturer	Route
Dose Life-Threaten 10 MG	Duration ning	Cerebrovascular Disorder			Abilify		PS		
10 MG					Adderall Xr		SS		
					Trileptal Soma		C C		
					Vicodin Mobic		C C		
Date:05/16/05 Age:10 YR G		: 4664213-6Report Type:Direct I/FU:I		Company Report	t #CTU 248668				
Outcome Dose	Duration	PT	Report	Source	Product		Role	Manufacturer	Route
Dose Other 15 MG CAP ONE	C	Blood Pressure Increased			Adderall Xr		PS		ORAL
PO Q AM		Headache							
		Weight Decreased							

Date:05/18/05ISR Number Age:21 YR Gender:Male	r: 4666485-0Report Type:Expedit e I/FU:I	ed (15-DaCompany Repor	t #SUSI-2005-00396			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization -	Dementia	Consumer	Adderall Xr			ļ
Initial or Prolonged	Drug Abuser		(Dextroamphetamine			ļ
	Insomnia		Sulfate,			ļ
	Mania		Dextroamphetamine			ļ
	Overdose		Saccharate,	PS		ORAL
30 MG, ORAL						ļ
4	Paranoia		Lexapro	С		
	Weight Decreased		Trazodone			ļ
			(Trazodone)	С		
Date:05/18/05ISR Number Age:17 YR Gender:Male	r: 4666486-2Report Type:Expedit e I/FU:I	ed (15-DaCompany Repor	t #SUSI-2005-00365			
Outcome	PT	Report Source	Product	Role	Manufacturer	Route

Dose	Duration		_			
Hospitali	zation -	Drug Hypersensitivity	Health	Adderall Xr		
Initial of	r Prolonged	Pleural Effusion	Professional	(Dextroamphetamine		
				Sulfate,Dextroamphet		
				amine Saccharate,		
				Amphetamine	PS	
				-		

30 MG, DAILY

Freedom Of Information (FOI) Report

Vitamin B12 For

(Cyanocobalamin)

С

Injection

Date:05/18/05ISR Number: 4666488-6Report Type:Expedited (15-DaCompany Report #SUSI-2005-00168 Age:7 YR Gender:Male I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Other		Angina Pectoris Cardiac Discomfort Cardiac Disorder	Consumer	Adderall (Dextroamphetamine Sulfate,			
		Cardiovascular Disorder		Dextroamphetamine			ł
		Drug Hypersensitivity		Saccharate,	PS		ORAL
15 MG,		Electrocardiogram					ľ
1X/DAY:QD,		Electrocararogram					,
		Abnormal					,
ORAL		- '					ľ
		Sneezing		Adderall (Dextroamphetamine Sulfate, Dextroamphetamine			
1				Saccharate,	SS		ORAL
10 MG,				baccharace,			010111
1X/DAY:QD,							
ORAL							
	5ISR Number Gender:Male	: 4666602-2Report Type:Expedi I/FU:I	ted (15-DaCompany Repo	rt #SUS1-2005-00398			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Prescribed Overdose Urinary Retention	Health Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine			
				Saccharate,	PS		
SEE IMAGE				Prozac (Fluoxetine Hydrochloride)	С		
				Prevacid (Lansoprazole)	С		

Date:05/24/05ISR Number Age:8 YR Gender:Male	r: 4673111-3Report Type:Direct e I/FU:I	Company Repor	rt #CTU 249307		
Outcome Dose Duration	PT	Report Source	Product	Role Manufacturer	Route
Hospitalization - ONE TAB Q AM	Blood Pressure Increased		Adderall Xr 15mg	PS	ORAL
Initial or Prolonged ORAL	Bone Pain				
Required	Crying				I
Intervention to	Dilatation Atrial				I
Prevent Permanent	Drug Toxicity				I
Impairment/Damage	Feeling Abnormal				I
	Heart Rate Increased				I
	Insomnia				
	Logorrhoea				
	Memory Impairment				
	Musculoskeletal Stiffness				
	Psychotic Disorder				
	Tic				

				FDA - Adverse	Event Reporting Syste	em (AER	S)	
				Freedom O	f Information (FOI) Re	eport		
Date:05/24/ Age:	/05ISR Number Gender:Male	: 4673142-3Report Type:Direct I/FU:I		Company Repor	t #CTU 249312			
Outcome	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Dose Death DAILY	Duración	Arrhythmia			Ritalin	PS		
		Atrial Fibrillation Cardiac Disorder Ejection Fraction Decreased Hypoaesthesia Incorrect Route Of Drug Administration			Adderall	SS		
	/05ISR Number Gender:Fema	: 4677627-5Report Type:Direct le I/FU:I		Company Repor	t #CTU 249596			
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Other	Daración	Drug Dose Omission			Adderall Xr 10g	Da		
ADDERALL XF	R	Drug Effect Decreased Unintended Pregnancy			2/05 -> 20g 3/05	PS		
10 - 20					Ortho Evra	SS		
ORTHO EVRA	?				OTCHO EVIA	55		
DOSE								
Date:05/27/ Age:	/05ISR Number Gender:	: 4675430-3Report Type:Periodi I/FU:I	с	Company Repor	t #US-BRISTOL-MYERS SÇ	QUIBB C	OMPANY-12885885	
Outcome	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
Dose	DULACION	Dyskinesia			Abilify	PS	Otsuka Pharmaceutical	
					Adderall Xr	SS	Company, Ltd.	

	)5ISR Number: Gender:	: 4675431-5Report T I/FU:I	'ype:Periodic	Company Repor	t #US-BRISTOL-MYERS \$	SQUIBB C	COMPANY-12885919	
Outcome Dose	Duration	PT	Report	Source	Product	Role	Manufacturer	Route
		Dyskinesia			Abilify Tabs	PS	Otsuka Pharmaceutical Company, Ltd.	
					Adderall Xr	SS	company, neu.	
Age:14 YR		· IO///OO ORCPOIC I	ype.Expedited (1)	-Dacompany Repor	t #SUS-2005-00401			
Outcome	Gender:Male	I/FU:I PT		Source	t #SUS-2005-00401 Product	Role	Manufacturer	Route
Dose	Duration	I/FU:I PT	Report	Source	Product	Role	Manufacturer	Route
	Duration	I/FU:I	Report Health	Source		Role	Manufacturer	Route

1X/DAY:QD

Freedom Of Information (FOI) Report

Date:05/27/05ISR Number: 4677762-1Report Type:Expedited (15-DaCompany Report #SUSI-2005-00405 Age:35 YR Gender:Female I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duration	Influenza Nephrolithiasis Pain Treatment Noncompliance	Health Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine Saccharate,	PS		
SEE IMAGE				, , , , , , , , , , , , , , , , , , ,			
				Amitriptyline (Amitriptyline) Soma (Carisoprodol) Lexapro (Escitalopram	C C		
				Oxalate)	С		
				Forvia	С		
				Flora-Q Polycitra-K "Willen" (Citric Acid	С		
				Monohydrate, Potassium Citrate)	С		
	Gender:Fema	: 4681636-XReport Type:Expedi le I/FU:F PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration		_				
Hospitalizat Initial or P Other		Convulsion Drooling	Health Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine			
				Saccharate,	PS		
	5ISR Number Gender:Male	: 4681637-1Report Type:Expedi e I/FU:F	ted (15-DaCompany Repo:	rt #SUS1-2005-00365			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P		Drug Hypersensitivity Eosinophil Percentage Increased	Health Professional	Adderall Xr (Dextroamphetamine			

	Pleural Effusion		Dextroamphetamine Saccharate,	PS	
30 MG DAILY,				-	
Date:06/02/05ISR Number Age:9 YR Gender:Male	r: 4681638-3Report Type:Exp e I/FU:I	pedited (15-DaCompany Re	eport #SUS1-2005-00429		
Outcome Dose Duration	РТ	Report Source	Product	Role Manufacturer	Route
Hospitalization - Initial or Prolonged	Bacterial Infection Pyrexia Rash Generalised Skin Exfoliation	Consumer	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine		
1X/DAY; QD,			Saccharate,	PS	
Date:06/02/05ISR Number Age:28 YR Gender:Male	r: 4681969-7Report Type:Exp = I/FU:I	edited (15-DaCompany Re	eport #SUS1-2005-00415		
Outcome Other	PT Affect Lability Anxiety				
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Freedom Of Information (FOI) Report

Daga	Dunchion	Drug Dependence Drug Ineffective Dysphemia	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Malaise Memory Impairment Muscle Tightness Thinking Abnormal	Consumer	Adderall Xr(Dextroamphetamine Sulfate, Dextroamphetamine	50		
20 MG,				Saccharate,	PS		
1X/DAY:QD							
	LTOD Number		12 - 1 (15 Dodompony D				
	51SR Number Gender:Male	: 4681972-7Report Type:Exped I/FU:I	lited (15-Dacompany Ke	port #SUS1-2005-00424			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat Initial or P	ion -	Cardiac Arrest Respiratory Arrest	Health Professional	Adderall Xr(Dextroamphetamine Sulfate, Dextroamphetamine	- 2		
5 MG, 1X/DAY				Saccharate,	PS		
IN AM							
	LICD Number	- 4602224 Persent Type. Direc					
	Gender:	: 4683324-2Report Type:Direc I/FU:I	Company Re	eport #USP 57183			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
CAPSULE,	Daracres	Drug Dispensing Error		Adderall	PS	Shire	
EXTENDED		Medication Error					
RELEASE							
	5ISR Number	: 4683328-XReport Type:Direc	ct Company Re	eport #USP 57182			

Age:

Gender:

I/FU:I

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration		Report Bource		ROIC		Route
CAPSULE,		Drug Dispensing Error		Adderall Xr 30 Mg	PS	Shire	
		Medication Error					
EXTENDED							
RELEASE							
	5ISR Number Gender:Male	: 4687389-3Report Type:Expedit	ed (15-DaCompany Report	t #DSA_26465_2005			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalizat 1 MG Q DAY		Aggression	Health	Ativan	PS		
Initial or P CAP	rolonged	Anxiety	Professional	Adderall	SS		
		Psychotic Disorder					
	5ISR Number Gender:Male	: 4693016-1Report Type:Expedit	ed (15-DaCompany Report	t #SUSI-2005-00451			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death		Prescribed Overdose	Health Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine			
20 10 10 / 510				Saccharate,	PS		
30 MG 1X/DAY	;						
QD				Adderall			
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Freedom Of Information (FOI) Report

(Dextroamphetamine Sulfate, Dextroamphetamine Saccharate, SS

90 MG,

1X/DAY; QD

Date:06/15/05ISR Number: 4693435-3Report Type:Expedited (15-DaCompany Report #USA-2005-0019662 Age:31 YR Gender:Male I/FU:F

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Death		Accidental Death	Consumer	Oxycontin			
Other		Alcohol Use	Health	Tablets(Oxycodone			
		Apnoea	Professional	Hydrochloride) Cr			
		Arterial Occlusive	Other	Tablet	PS		
		Disease		Amphetamine(Amphetam			
		Cardiac Arrest		ine Sulfate)	SS		
		Cardiac Failure		Alcohol(Ethanol)	SS		
		Congestive		Adderall(Dexamfetami			
		Depression		ne			
		Disseminated		Saccharate,Amfetamin			
		Intravascular Coagulation		e			
		Drug Toxicity		Sulfate,Dexamfetamin	SS		
		Dyspnoea		Zyprexa (Olanzapine)	С		
		Haemorrhagic Disorder		Valium (Diazepam)	С		
		Hypertensive Heart		Temazepam			
		Disease		(Temazepam)	С		
		Injury Asphyxiation		Antihypertensives	С		
		Loss Of Consciousness					
		Mountain Sickness Acute					
		Multiple Drug Overdose					
		Accidental					
		Polysubstance Abuse					
		Pulmonary Thrombosis					
		Thrombosis					
		Urine Alcohol Test					
		Positive					
		Vomiting					

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
		Disturbance In Attention		Adderall (Generic )			
		Pharmaceutical Product		30 Mg Once Q Am Po	PS		ORAL
30 MG, Q AM	,						
		Complaint					
PO							
Data:06/22/	ALTOD Numbor	: 4697689-9Report Type:Exped	itad (15-DaCompany Pa				
Age:18 YR	Gender:Fema		ited (15-Dacompany Re	2001C #SUS1-2003-00483			
ngerio in	Gender + I elle						
Outcome		PT	Report Source	Product	Role	Manufacturer	
Dose				Product	<b>VOTE</b>		Route
DOSE	Duration			Product	KOIE		Route
Disability	Duration	Tic	Consumer	Adderall(Dextroamphe	KOIE		Route
	Duration	Tic Wheelchair User	Consumer		KOIE		Route
	Duration		Consumer	Adderall(Dextroamphe	KOIE		Route
	Duration		Consumer	Adderall(Dextroamphe tamine Saccharate,	KOIE		Route

Freedom Of Information (FOI) Report

Date:06/22/05ISR Number: 4697690-5Report Type:Expedited (15-DaCompany Report #SUSI-2005-00036 Age:13 YR Gender:Male I/FU:F

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other	Duración	Abasia Condition Aggravated Muscle Spasticity Pain	Consumer	Adderall Xr(Dextroamphetamine Sulfate, Dextroamphetamine Saccharate,	PS		ORAL
15 MG,				Saccilar acc,	ΓU		UKAL
1X/DAY;QD,							
ORAL				Concerta (Methylphenidate Hydrochloride)	С		
	)5ISR Number Gender:Male	r: 4697692-9Report Type:Expedito I/FU:I	ed (15-DaCompany Repor	t #SUSI-2005-00474			
Outcome Dose Other SEE IMAGE	Duration	PT Intentional Misuse Off Label Use Optic Neuritis Overdose Papilloedema Retinal Haemorrhage Retinal Vein Occlusion Visual Disturbance	Report Source Health Professional	Product Adderall(Dextroamphe tamine Sulfate, Dextroamphetamine Saccharate, Amphetamine Sulfate,		Manufacturer	Route
	)5ISR Number Gender:Fema	r: 4699056-0Report Type:Direct ale I/FU:I	Company Report	t #CTU 251761			
Outcome Dose Other 1 TAB/DAILY	Duration	PT Fatigue	Report Source	Product Cymbalta 30 Mg	Role PS	Manufacturer	Route ORAL
BY MOUTH	4 WK	Feeling Abnormal					

		Migraine		Adderall Xr 20mg	SS	ORAL
1 TAB/DAILY						
BY MOUTH	1 DA	ΥY		Ranitidine	С	
	5ISR Numbe Gender:Mal	er: 4707015-4Report Type:E .e I/FU:I	Expedited (15-DaCompany Ro	eport #SUSI-2005-00513		
Outcome		PT	Report Source	Product	Role Manufacturer	Route
Dose	Duration					
Other		Agitation	Consumer	Adderall Xr		
		Bradyphrenia		(Dextroamphetamine		
		Delusion		Sulfate,		
		Depression		Dextroamphetamine		
		Euphoric Mood		Saccharate,	PS	
		Eye Pain		Abilify		
		Fatigue		(Aripiprazole)	С	
		Feeling Abnormal				
		Hyperventilation				

Social Avoidant Behaviour

Vomiting

FDA - Adverse Event Reporting System (AERS) Freedom Of Information (FOI) Report Date:07/01/05ISR Number: 4707021-XReport Type:Expedited (15-DaCompany Report #SUSI-2005-00510 Gender:Female Aqe:22 YR I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Life-Threatening Cardiac Arrest Health Adderall Xr Hospitalization -Loss Of Consciousness Professional (Dextroamphetamine Initial or Prolonged Syncope Sulfate, Dextroamphetamine Saccharate, PS Date:07/01/05ISR Number: 4707208-6Report Type:Direct Company Report #CTU 252413 Age:7 YR Gender:Female I/FU:I Report Source Role Manufacturer Outcome PTProduct Route Duration Dose Aggression Adderall Xr 10 Mg PS ORAL Other 1 DAY ORAL Required Agitation Intervention to Bipolar Disorder Prevent Permanent Hostility Impairment/Damage Irritability Date:07/01/05ISR Number: 4707275-XReport Type:Direct Company Report #CTU 252425 Age:8 YR Gender:Female I/FU:I Outcome PTReport Source Product Role Manufacturer Route Dose Duration Other Aggression Adderall Xr 30 Mg PS ORAL 30MG ONCE Anger PER DAY Physical Assault ORAL Self-Injurious Ideation Ritalin La Ni SS ORAL ONCE PER DAY

ORAL

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 30 MG PO	Duración	Drug Effect Decreased Pharmaceutical Product Complaint		Adderall	PS		ORAL
	5ISR Number Gender:Male	: 4708999-0Report Type:Expedit I/FU:F	ed (15-DaCompany Repor	t #STXI-2002-00385			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Death	Duración	Fall Sudden Cardiac Death	Health Professional Company Representative	Adderall Xr (Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine	PS		
10 mg, one dose							
	5ISR Number Gender:Fema	: 4711581-2Report Type:Direct le I/FU:I	Company Report	t #CTU 252860			
Outcome	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other 1 CAP QD PO	DULACION	Drug Dispensing Error		Adderall Xr 20 Mg	PS		ORAL

Freedom Of Information (FOI) Report

Date:07/11/05ISR Number: 4711476-4Report Type:Expedited (15-DaCompany Report #SUS1-2005-00509 Age:14 YR Gender:Male I/FU:I

Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Dose Other	Duracion	Petit Mal Epilepsy	Consumer	Adderall(Dextroamphe tamikne Sulfate, Dextroamphetamine Saccharate,			
				Amphetamine Sulfate,	PS		
Date:07/12/( Age:7 YR	)5ISR Number Gender:Male	r: 4711939-1Report Type:Expedit e I/FU:I	ed (15-DaCompany Repor	t #PHEH2005US07492			
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other		Duodenal Ulcer		Ritalin	PS	Novartis Sector: Pharma	
10 mg, QD				Adderall	SS		
10 mg IINK				Concerta	C		
18 mg, UNK				Remeron	С		
7.5 mg, UNK				Melatonin	С		I
				Belladonna Extract	С		
30 mg, UNK				Prevacid	С		
5.				Zithromax Z-Pack	С		
Date:07/12/0	)5ISR Number	: 4712970-2Report Type:Direct	Company Repor	rt #CTU 253020			
	Gender:Male						I
Outcome Dose	Duration	PT	Report Source	Product	Role	Manufacturer	Route
Other 10 MG, 1 TIN		Feeling Abnormal		Adderall Xr 10 Mg	PS		ORAL
		Nightmare					
DAILY, ORAL							
		Palpitations Pharmaceutical Product Complaint					
1							<b>/</b>

Sleep Terror

Date:07/13/05ISR Number: 4715865-3Report Type:Expedited (15-DaCompany Report #SUS1-2005-00523 Age: Gender:Male I/FU:I

Outcome Dose Du	uration	PT	Report Source	Product	Role	Manufacturer	Route
Other	]		Professional	Adderall Xr (Dextroamphetamine Sulfate, Dextroampethamine Saccharate,	PS		

Date:07/13/05ISR Number: 4715869-0Report Type:Expedited (15-DaCompany Report #SUS1-2005-00525 Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route
Dose Duration						
Hospitalization - Initial or Prolonged	Aggression Anger Anxiety Irritability Paranoia	Consumer	Adderall Xr(Dextroamphetamine Sulfate, Dextroamphetamine Saccharate,	PS		
20 MG,						
1X/DAY;QD						
			Depakote (Valproate Semisodium) Effexor (Venlafaxine	С		

Freedom Of Information (FOI) Report

Hydrochloride)	С
Docusate (Docusate0	С
Promethazine	
(Promethazine)	С
Inderal La	
(Propranolol	
Hydrochloride)	С
Famotidine	
(Famotidine)	С
Frova/01623201/(Frov	
atriptan)	С
Fiorinal	
(Butalbital,	
Caffeine,	
Acetylsalicylic	
Acid)	С
Ibuprofen	
(Ibuprofen)	С
Hydrocodone	
W/Ibuprofen	
(Ibuprofen,	
Hydrocodone)	С
Tizanidine	
(Tizanidine)	С

Date:07/20/05ISR Number: 4722724-9Report Type:Expedited (15-DaCompany Report #SUS1-2005-00545 Age:10 YR Gender:Male I/FU:I

Outcome Dose Duration	PT	Report Source	Product	Role	Manufacturer	Route
Hospitalization - Initial or Prolonged	Dehydration Diarrhoea Disorientation Drug Therapy Changed Headache	Consumer	Adderall Xr (Dextroamphetamine Sulfate, Dextroamphetamine Saccharate,	PS		ORAL
SEE IMAGE	Prescribed Overdose Vomiting		Seroquel (Quetiapine Fumarate) Paxil Cr (Paroxetine Hydrochloride)	C C		OTT

Outcome		PT	Report Source	Product	Role	Manufacturer	Route
Dose	Duration						
Hospitalizat	cion -	Abnormal Behaviour	Consumer	Adderall Xr			
Initial or H	Prolonged	Depression		(Dextroamphetamine			
		Mood Swings		Sulfate,			
		Prescribed Overdose		Dextroamphetamine			
		Psychotic Disorder		Saccharate,	PS		ORAL
SEE IMAGE							
				Paxil Cr (Paroxetine			
				Hydrochloride)	С		
				Seroquel (Quetiapine			
				Fumarate)	С		

Date:07/26/05ISR Number: 4726064-3Report Type:Direct Age:11 YR Gender:Male I/FU:I Company Report #CTU 254314

- Outcome Life-Threatening Hospitalization -
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Freedom Of Information (FOI) Report

Initial or Prolong	Jed				
Disability					
Required				-	
Intervention to Dose Durat	PT	Report Source	Product	Role Manufacturer	Route
Prevent Permanent 20MG Q DAY	Bipolar Disorder		Adderall Xr	PS	ORAL
Impairment/Damage ORAL	Depression				
	Hallucination, Auditory		Paxil	SS	ORAL
20MG Q DAY					
	Homicidal Ideation				
ORAL	M			2	
	Mania		Adderall Xr	C	
	Psychotic Disorder		Zyprexa	C	
	Suicidal Ideation		Paxil	C	
1			Lithium	C	
			Depakote	C	
			Zyprexa	С	
1			Geodon	С	
			Trileptal	С	
			Clonidine	C	
			Klonipin	С	
			Ambien	C	
			Strattera	C	
			Remeron	C	
			Abilify	C	
Date:08/01/05ISR M Age:16 YR Gender	Jumber: 4732438-7Report Type:Exp r:Male I/FU:F	edited (15-DaCompany Re	eport #SUS1-2005-00401		
Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Durat					
Other	Arrhythmia	Health	Adderall Xr		
	Chest Pain	Professional	(Dextroamphetamine		
	Electrocardiogram T Wave		Sulfate,		
	Inversion		Dextroamphetamine		
I	Feeling Abnormal		Saccharate, Amphetami	PS	
25 MG IN	2		_		
	Muscle Strain				
MORNING					
			Claritin		
1				a	

(Loratadine) C

Outcome	PT	Report Source	Product	Role Manufacturer	Route
Dose Duration Hospitalization -	Abnormal Behaviour	Consumer	Adderall Xr		
Initial or Prolonged	Depression	Consumer	(Dextroamphetamine		
	Disturbance In Attention		Sulfate,		
	Mood Swings		Dextroamphetamine		
	Prescribed Overdose		Saccharate,	PS	ORAL
10 MG 1X/DAY	Davahatia Digondon				
QD ORAL	Psychotic Disorder				
			Paxil Cr(Paroxetine		
			Hydrochloride)	С	
			Seroquel (Quetiapine		
			Fumarate)	C	
Date:08/01/05ISR Numbe	r: 4732478-8Report Type:Exped	ited (15-DaCompany Re	eport #SUS1-2005-00545		
Date:08/01/05ISR Numbe Age:10 YR Gender:Mal		ited (15-DaCompany Re	eport #SUS1-2005-00545		
		ited (15-DaCompany Re	eport #SUS1-2005-00545		
Age:10 YR Gender:Mal	e I/FU:F	ited (15-DaCompany Re	eport #SUS1-2005-00545		
Age:10 YR Gender:Mal Outcome	e I/FU:F PT Crying Dehydration	ited (15-DaCompany Re	eport #SUS1-2005-00545		
Age:10 YR Gender:Mal Outcome Hospitalization -	e I/FU:F PT Crying Dehydration Diarrhoea	ited (15-DaCompany Re	eport #SUS1-2005-00545		
Age:10 YR Gender:Mal Outcome Hospitalization -	e I/FU:F PT Crying Dehydration	ited (15-DaCompany Re	eport #SUS1-2005-00545		
Age:10 YR Gender:Mal Outcome Hospitalization -	e I/FU:F PT Crying Dehydration Diarrhoea	ited (15-DaCompany Re	eport #SUS1-2005-00545		

Freedom Of Information (FOI) Report

		Disturbance In Attention Drug Therapy Changed Headache	Report Source	Product	Role	Manufacturer	Route
Dose	Duration	Prescribed Overdose Vomiting	Consumer	Adderall Xr (Dextroamphetamine Sulfate,			
				Dextroamphetamine Saccharate,	PS		ORAL
SEE IMAGE				Seroquel (Quetiapine			
				Fumarate) Paxil Cr (Paroxetine	C		
				Hydrochloride)	С		
Date:08/01/ Age:22 YR	05ISR Number Gender:Male	r: 4732480-6Report Type:Exped e I/FU:F	ited (15-DaCompany Re	eport #SUS1-2005-00513			
			ited (15-DaCompany Re	eport #SUS1-2005-00513			
			ited (15-DaCompany Re Report Source Consumer	eport #SUS1-2005-00513 Product Adderall Xr (Dextroamphetamine	Role	Manufacturer	Route
Age:22 YR Outcome Dose	Gender:Male	PT Agitation	Report Source	Product Adderall Xr	Role	Manufacturer	Route

Freedom Of Information (FOI) Report

Summary report for FOI selections:

Selection by inexact search of active ingredient:

NOINGRED%

Selection by inexact search of Tradename/Verbatim:

ADDERALL%

Total number of reports: 1,048

From: 01-NOV-1997 To: Present