

Public Case Detail

Cases Count: 21

Case Number : 195519

Gender : M

Data Entry Date : 16/03/2004

Weight (kg) : 66

Hospitalisation :

Age :

Onset Date :

DOB : 18/12/1987

Outcome :

Causality : Causality probable

Recovered

Information: Changed to Ritalin LA 40 mg and Ritalin 20 mg and has been fine since

Reaction :

Preferred Term	Severity	Report Description	Treatment
Headache		Headaches, sweating, mood swings, not eating. Had to be sent home from work 3 days in a row.	Ceased Concerta, changed to Ritalin
Decreased appetite			
Hyperhidrosis			
Mood swings			

Medicine details :

Concerta (Suspected)		Reason : Behavior disorders of childhood	
Tablet	36 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
Zactin (Other drug)		Reason : Depression	
	20 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 21

Case Number : 212069

Data Entry Date : 28/09/2005

Gender : M

Hospitalisation :

Weight (kg) : 38

Onset Date : 23/09/2005

Age : 13Y

Outcome :

DOB :

Not yet recovered

Causality : Causality certain

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Dystonia	Incapacity/disability	Dystonic reaction. Unusual movement of legs, rolling of body. Reproduced on reintroduction of Methylphenidate (different brand).	Removal of Prozac and Concerta. On retrial of Methylphenidate was given Cogentin with result for Dystonia
Dyskinesia	Incapacity/disability		

Medicine details :

Concerta (Suspected)	Reason :
Capsule	54 Milligram Daily Oral
Batch :	Started : 01/01/1998 Stopped :
Catapres (Other drug)	Reason :
Tablet	350 Milligram Daily Oral
Batch :	Started : 01/01/1998 Stopped :
Prozac (Other drug)	Reason :
Capsule	20 Milligram Daily Oral
Batch :	Started : 01/01/1998 Stopped :

Public Case Detail

Cases Count: 21

Case Number : 221441

Data Entry Date : 06/09/2006

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Tourette's disorder		Tourette's disorder, hyperhidrosis.	
Tic		Tourette's syndrome	
Hyperhidrosis			

Medicine details :			
Concerta (Suspected)		Reason :	
Tablet			Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 21

Case Number : 228510

Gender : M

Data Entry Date : 15/05/2007

Weight (kg) : 0

Hospitalisation :

Age : 11Y

Onset Date : 05/05/2007

DOB :

Outcome :

Causality : Causality possible

Unknown

Information: Previously taking Ritalin

Reaction :

Preferred Term	Severity	Report Description	Treatment
Aggression		Described as being out of control, bashing windows, kicking hole through the wall, broke tree branches, let the air out of car tyres	
Disturbance in social behaviour			

Medicine details :

Concerta (Suspected)		Reason :	
Tablet	36 Milligram	1 time	Oral
Batch :	Started : 02/05/2007	Stopped :	0

Public Case Detail

Cases Count: 21

Case Number : 230977

Data Entry Date : 17/07/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/05/2007

Age : 10Y

Outcome :

DOB :

Recovered

Causality : Causality probable

Information: Patient was stable on ritalin 10mg/bd.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Condition aggravated		After child was switched from Ritalin to Concerta, his condition of ADHD worsened.	Concerta stopped and switched back to Ritalin.

Medicine details :

Concerta (Suspected)	Reason : Behavior disorders of childhood		
Tablet	36 Milligram	Daily	Oral
Batch :	Started : 16/04/2007	Stopped : 16/06/2007	

Public Case Detail

Cases Count: 21

Case Number : 232726

Gender : M

Data Entry Date : 29/08/2007

Weight (kg) : 27.8

Hospitalisation : Required a visit to the doctor

Age :

Onset Date :

DOB : 28/06/2000

Outcome :

Causality : Causality probable

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Hallucination		Major hallucinations on long acting but no similar problems with short acting.	

Medicine details :			
Concerta (Suspected)		Reason : Behavior disorders of childhood	
Tablet	18 Milligram	Daily	Oral
Batch :	Started : 19/05/2007	Stopped : 22/05/2007	
Catapres (Other drug)		Reason : Specific disorders of sleep	
	100 Microgram	Daily	
Batch :	Started :	Stopped : 23/02/2005	

Public Case Detail

Cases Count: 21

Case Number : 235980

Data Entry Date : 06/12/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 14Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Henoch-Schonlein purpura		Henoch-Schonlein Purpura	

Medicine details :

Concerta (Suspected)		Reason :	
Tablet	36 Milligram	Oral	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 21

Case Number : 236564

Data Entry Date : 28/12/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 10Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Paranoia		frightened and paranoid about insects	
Weight increased		in 6 months from 6 stone to 11 stone	
Hyperaesthesia		intolerable to touch	
Tic		tic like behaviours, shrugging and head nodding occurred one month after starting concerta	
Fear			
Muscle twitching			

Medicine details :			
Concerta (Suspected)		Reason :	
	36 Milligram		Oral
Batch :	Started :	Stopped :	0
Movox (Other drug)		Reason :	
			Oral
Batch :	Started :	Stopped :	
Risperdal (Other drug)		Reason :	
	1 Milligram	2 times	Oral
Batch :	Started : 30/06/2005	Stopped :	

Public Case Detail

Cases Count: 21

Case Number : 236763

Data Entry Date : 08/01/2008

Gender : F

Hospitalisation :

Weight (kg) : 34.2

Onset Date : 20/11/2007

Age :

DOB : 17/05/2001

Outcome : 25/11/2007

Causality : Causality possible

Recovered

Information: A few of my patients have had this issue ? absorption/capsule dissolving issue. Not really an adverse reaction, but I thought it worth mentioning.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug ineffective		Changed from Ritalin 10mg/tds to Concerta 27mg/daily. Concerta had no effect at all "as if she was taking nothing". Parents certain she was swallowing the medication.	Changed back to Ritalin 10mg with good effect.

Medicine details :

Concerta (Suspected)

Reason : Behavior disorders of childhood

Tablet

27 Milligram

Daily

Oral

Batch :

Started : 20/11/2007

Stopped : 24/11/2007

Public Case Detail

Cases Count: 21

Case Number : 237114

Data Entry Date : 21/01/2008

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 29

Onset Date : 01/03/2007

Age :

DOB : 18/11/1997

Outcome : 15/11/2007

Causality : Causality probable

Recovered

Information: ADHD/ASD with no medication able to be taken.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Decreased appetite		Patient experienced loss of appetite, insomnia, skin sores, (scratching of skin sores), head banging on walls, psychosis, violent self harming behaviour with rages lasting up to 1 hour.	Medications ceased.
Aggression			
Head banging			
Insomnia			
Self injurious behaviour			
Skin lesion			

Medicine details :

Concerta (Suspected)		Reason : Behavior disorders of childhood	
Tablet	18 Milligram	Daily	Oral
Batch :	Started : 01/03/2007	Stopped : 31/10/2007	

Public Case Detail

Cases Count: 21

Case Number : 239592

Data Entry Date : 03/04/2008

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 38

Onset Date : 07/01/2008

Age :

DOB : 30/12/1999

Outcome : 09/01/2008

Causality : Causality probable

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hallucination		Child with ADHD had been taking ritalin for some time with good effect and no side effects. Tried switching to Concerta for ease of dosage. Within 7 days developed hallucinations (spiders and 'trolls'). Drug was withdrawn and hallucinations stopped.	Concerta withdrawn

Medicine details :

Concerta (Suspected)	Reason : Behavior disorders of childhood
	36 Milligram Daily
Batch :	Started : 01/01/2008 Stopped : 08/01/2008

Public Case Detail

Cases Count: 21

Case Number : 245260

Data Entry Date : 08/10/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 25/08/2008

Age : 14Y

Outcome :

DOB :

Recovered

Causality : Causality probable

Information: The patient's outcome was unknown for anaphylactic shock. Action taken with OROS methylphenidate hydrochloride was unknown. This report was serious (medically significant). Anaphylaxis is "rare" in PI.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Anaphylactic shock		On an unspecified date, the patient experienced anaphylactic shock after using OROS methylphenidate hydrochloride first time. The patient had switched from dexamphetamine to OROS methylphenidate hydrochloride.	
Dyspnoea			
Wheezing			

Medicine details :

Concerta (Suspected)	Reason :		
Tablet	54 Milligram	Oral	
Batch :	Started : 25/08/2008	Stopped :	0
Dexamphetamine Sulphate (Other drug)	Reason :		
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 21

Case Number : 245381

Data Entry Date : 13/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 22.8

Onset Date :

Age : 7Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Tic		Severe tics (body shuddering/shaking and vocal tics) and headache. Condition worsened each day.	
Headache			
Tremor			

Medicine details :			
Concerta (Suspected)		Reason :	
		18 Milligram	Daily
Batch :	Started :	Stopped :	
Risperdal (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 21

Case Number : 248338

Data Entry Date : 06/02/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 01/12/2008

Age :

DOB : 02/08/1986

Outcome :

Causality : Causality possible

Unknown

Information: Medical history: Trisomy 21 (Down's syndrome), ongoing.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug ineffective		Patient experienced exacerbation of autism and breakthrough of symptoms. No known other illicit or other drug use.	
Therapeutic response decreased			

Medicine details :

Concerta (Suspected)		Reason : Down's disease	
Tablet	54 Milligram	Daily	Oral
Batch :	Started :	Stopped : 16/02/2009	0

Public Case Detail

Cases Count: 21

Case Number : 248358

Data Entry Date : 06/02/2009

Gender : M

Hospitalisation :

Weight (kg) : 73

Onset Date :

Age :

DOB : 02/10/1992

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Haematuria		Patient developed loin pain and haematuria and chronic cystitis.	
Back pain			
Cystitis			

Medicine details :

Concerta (Suspected)	Reason : Behavior disorders of childhood
Batch :	Started : 22/07/2008
	Stopped : 16/10/2008

Public Case Detail

Cases Count: 21

Case Number : 252374

Data Entry Date : 16/06/2009

Gender : M

Hospitalisation :

Weight (kg) : 46

Onset Date : 12/05/2009

Age :

DOB : 29/04/1997

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Agitation	Incapacity/disability	Increased agitation, abdominal pain, aches, photophobia, decreased sleep, poor concentration	cease drug
Abdominal pain	Incapacity/disability		
Disturbance in attention	Incapacity/disability		
Drug ineffective	Incapacity/disability		
Insomnia	Incapacity/disability		
Pain	Incapacity/disability		
Photophobia	Incapacity/disability		

Medicine details :

Concerta (Suspected)	Reason :		
Capsule, modified release	54 Milligram	Daily	Oral
Batch :	Started : 12/05/2009	Stopped : 16/06/2009	

Public Case Detail

Cases Count: 21

Case Number : 254115

Data Entry Date : 19/07/2009

Gender : M

Hospitalisation :

Weight (kg) : 40

Onset Date :

Age : 15Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Obsessive-compulsive disorder		OBSESSIVE COMPULSIVE DISORDER WITH COMPULSION TAKING UP TO 2HRS/DAY AND IMPACTING ON THE FAMILY.	PHYSICIAN IS TRAILING A LOWER DOSE OF OROS TO SEE IF OCD RESOLVES.

Medicine details :

Concerta (Suspected)		Reason :	
	34 Milligram		Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 21

Case Number : 254470

Data Entry Date : 26/07/2009

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 14Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Syncope		syncope	

Medicine details :			
Concerta (Suspected)		Reason :	
		Daily	Oral
Batch :	Started :	Stopped :	
_____	_____	_____	

Case Number : 255101

Data Entry Date : 08/08/2009

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 17/04/1997

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Migraine with aura		Patient experienced visual accommodation difficulty and patient was no longer able to read words or music, patient had features of migrainous aura wavy lines, zig-zags, swirls and very mild headache.	Ceased Concerta
Accommodation disorder			

Medicine details :

Concerta (Suspected)		Reason : Behavior disorders of childhood	
Tablet	36 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
Evening Primrose Oil (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 21

Case Number : 255720

Data Entry Date : 21/08/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99U

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Lens disorder		Patient was treated with Concerta 27 mg initiated on an unknown date to Sep 2008, then 18mg to May 2009 and 27 mg to the present day. On unknown date the patient experienced spots on both lenses.	

Medicine details :			
Concerta (Suspected)		Reason : Behavior disorders of childhood	
Tablet	27 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Selection Parameters : Date Range: 01/01/1960 To 31/08/2009 Medicine Status: General marketing Unclear causality excluded Medicine Names: Concerta