

Case Number: 195519

Gender: M

Ritalin

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:

Anorexia

Hyperhidrosis Mood swings

Batch:

Preferred Term Severity Report Description Treatment

Headaches, sweating, Ceased Concerta, changed to

mood swings, not eating.

Had to be sent home from

Stopped:

work 3

days in a row.

Medicine details :

Concerta (Suspected) Reason: Behavior disorders of childhod

Tablet 36 Milligram Daily Oral

ZACTIN (Other drug) Reason : Depression

Started:

20 Milliarem Deile

20 Milligram Daily Oral

Batch: Started: Stopped:

PUSIME02 Page 1 of 12



Case Number : 212069

Gender: M

Data Entry Date: 28/09/2005 **Weight (kg)**: 38

Hospitalisation: Age: 13Y

Onset Date: 23/09/2005 **DOB**:

Outcome: Causality: Causality certain

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dystonia Incapacity/disability Dystonic reaction. Unusual Removal of

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:

PUSIME02 Page 2 of 12



Case Number: 221441 Gender: F

Data Entry Date: 06/09/2006 Weight (kg): 0

Hospitalisation: Age: 99Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Tourette's disorder, hyperhidrosis.

Tic Tourette's syndrome

Hyperhidrosis

Medicine details:

Concerta (Suspected) Reason :

Tablet Oral

Batch: Started: Stopped:

PUSIME02 Page 3 of 12



Hospitalisation:

Public Case Detail

Case Number: 225390

Gender: M

Data Entry Date: 05/02/2007 **Weight (kg)**: 34

Age:

Onset Date: 15/01/2007 DOB: 17/12/1997

Outcome: Causality: Causality possible

Recovered with sequelae

Information: Medical History: Asperger's disorder borderline.

Reaction:

Preferred Term Severity Report Description Treatment

Dyskinesia Incapacity/disability Developed facial tic, facial Treatment withdrawn.

contortions, anger, obsessive play with toys and he was emotional and

talkative.

Anger Incapacity/disability

Emotional disorder Incapacity/disability

Logorrhoea Incapacity/disability
Obsessive thoughts Incapacity/disability

Tic Incapacity/disability

Medicine details:

Concerta (Suspected) Reason: Behavior disorders of childhod

Tablet 36 Milligram Daily Oral

Batch: **Started**: 15/01/2007 **Stopped**: 15/01/2007

RISPERDAL (Other drug) Reason :

Batch: Started: Stopped:

PUSIME02 Page 4 of 12



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: Previosly 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

Tablet

Medicine details:

Concerta (Suspected)

Reason:

1 time

Oral

Batch:

Started: 02/05/2007

36 Milligram

Stopped: 0

PUSIME02

Page 5 of 12



Case Number: 230977

Gender: M

Data Entry Date: 17/07/2007

Weight (kg): 0

Hospitalisation:

Age: 10Y

Onset Date: 15/05/2007

DOB:

Outcome:

Causality: Causality probable

Recovered

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,

Concerta stopped and switched back to Ritalin.

his condition of ADHD

worsened.

Medicine details:

Concerta (Suspected)

Reason: Behavior disorders of childhod

Tablet

36 Milligram

Daily

Oral

Batch:

Started: 16/04/2007

Stopped: 16/06/2007

PUSIME02 Page 6 of 12



Onset Date:

Public Case Detail

Case Number: 232726

Gender: M

Age:

Data Entry Date: 29/08/2007 **Weight (kg)**: 27.8

Hospitalisation: Required a visit to the doctor

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 childhod

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

PUSIME02 Page 7 of 12



Case Number: 235980

Gender: M

Data Entry Date: 06/12/2007 **Weight (kg)**: 0

Hospitalisation: Age: 14Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

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:

PUSIME02 Page 8 of 12



Case Number: 236564 Gender: M

Data Entry Date: 28/12/2007 **Weight (kg)**: 0

Hospitalisation: Age: 10Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

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 occured 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:

PUSIME02 Page 9 of 12



Hospitalisation:

Public Case Detail

Case Number : 236763

Gender: F

Data Entry Date: 08/01/2008 **Weight (kg)**: 34.2

Age:

Onset Date: 20/11/2007 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 werth mentioning.

Reaction:

Preferred Term Severity Report Description Treatment

Drug ineffective Changed from Ritalin Changed back to Ritalin 10mg 10mg/tds to Concerta with good effect.

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.

Medicine details:

Concerta (Suspected) Reason : Behavior disorders of childhod

Tablet 27 Milligram Daily Oral

Batch: **Started**: 20/11/2007 **Stopped**: 24/11/2007

PUSIME02 Page 10 of 12



Case Number: 237114

Gender: M

Data Entry Date: 21/01/2008

Weight (kg): 29

Hospitalisation: Required a visit to the doctor

Age:

Onset Date: 01/03/2007

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

Anorexia

Patient experienced loss of Medications ceased. appetite, insomnia, skin

sores, (scratching of skin sores), head banging on walls, psychosis, violent self harming behaviour with rages lasting up to 1

hour.

Aggression

Head banging

Insomnia

Self injurious behaviour

Skin lesion

Medicine details:

Concerta (Suspected)

Reason: Behavior disorders of childhod

Tablet

18 Milligram

Daily

Oral

Batch:

Started: 01/03/2007

Stopped: 31/10/2007

PUSIME02 Page 11 of 12



Case Number: 239592

Gender: M

Data Entry Date: 03/04/2008 **Weight (kg)**: 38

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 07/01/2008 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 Concerta withdrawn

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.

Medicine details:

Concerta (Suspected) Reason: Behavior disorders of childhod

36 Milligram Daily

Batch: Started: 01/01/2008 **Stopped:** 08/01/2008

Selection Parameters: Date Range: 01/01/1960 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: Concerta

PUSIME02 Page 12 of 12