

Cases Count: 144

Case Number: 24167

Data Entry Date: 10/12/1980 Weight (kg):

Hospitalisation: Age: 59Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Recovered

Information: Pat. has been using warfarin long term. see report for concurrent therapy.

Reaction:

Preferred Term Severity Report Description Treatment

Prothrombin level decreased Drugs withdrawn.

Medicine details:

Ritalin (Interaction) Reason : Otr prim malig n lymphoid tisu

Tablet 20 Milligram Daily Oral

Batch: **Started**: **Stopped**: 06/10/1980

Warfarin Sodium (Interaction) Reason : Otr prim malig n lymphoid tisu

Tablet 7.5 Milligram Alternate days Oral

Batch: **Started**: **Stopped**: 06/10/1980

Warfarin Sodium (Interaction) Reason : Otr prim malig n lymphoid tisu

Tablet 5 Milligram Alternate days Oral

Batch: **Started**: **Stopped**: 06/10/1980

Laboratory Investigations:

Type Range Date Tested Result Details

Haematology 1 day 1 thrombotest < 3%

day 2 thrombotest 10%

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Cases Count: 144

Case Number: 24796

Gender: F

Data Entry Date: 13/03/1981

Weight (kg): 53

DOB:

Hospitalisation:

Outcome:

Onset Date: 22/02/1981

Age: 70Y

Causality: Causality possible

Recovered

Information: Patient history of pulmonary embolus, impaired renal function, hypokalaemia u.t.i.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Dementia

Hypotension

Ritalin ceased.

Peripheral ischaemia

Medicine details:

Ritalin (Suspected)

Reason:

Tablet

10 Milligram

Daily

Oral

Batch:

Started:

Stopped: 25/02/1981

Aspro Clear (Other drug)

Reason: Pain

Tablet

Batch:

2 Dose Unspec Daily

Oral

CONTIN

Codeine Phosphate (Other drug)

Reason: Diarrhea

Oral

Tablet Batch: 30 Milligram

Daily

Started: 21/02/1981

Started: 20/02/1981

Stopped: 21/02/1981

Stopped:

Maxolon (Other drug)

10 Milligram

Daily

Reason: Nausea and vomiting

Oral

Batch:

Tablet

Started: 20/02/1981

Stopped: 22/02/1981

Nitrazepam (Other drug)

Reason: Specific disorders of sleep 5 Milligram

Daily

Tablet

Batch:

Started: 20/02/1981

Stopped: 21/02/1981

Laboratory Investigations:

Type

Range

Date Tested Result

Details

Electrographics Ecg showed some ischaemic changes

with hypotension.

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Cases Count: 144

Case Number: 25836 Gender: M

Data Entry Date: 01/09/1981 Weight (kg):

Hospitalisation: Age: 05Y

Onset Date: 22/07/1981 **DOB**:

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dyskinesia

Dystonia

Extrapyramidal disorder Ritalin withdrawal.

Oculogyric crisis

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 10 Milligram 1 time Oral

Batch: **Started**: 22/07/1981 **Stopped**: 22/07/1981

Clonazepam (Other drug) Reason : Other&unspecified epilepsy

Solution 48 Dose Unspec Daily Oral

Batch: Started: Stopped:

Epilim (Other drug) Reason : Other&unspecified epilepsy

700 Milligram Daily

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 74013

Gender: F

Data Entry Date: 29/10/1991

Weight (kg): 61

Hospitalisation:

Age: 81Y

Onset Date: 31/08/1991

DOB:

L

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Chest pain

Left sided chest discomfort.

Dyspnoea

Oxygen, frusemide, morphine

and verapamil.

Palpitations

Medicine details:

Chlorpropamide (Suspected)

Reason:

2 Dose Unspec Daily

Batch :

Started :

Stopped: 01/09/1991

Ritalin (Suspected)

Reason:

1 Dose Unspec Daily

Batch :

, ,

Stopped: 31/08/1991

Aspirin (Other drug)

Batch:

Reason :

Daily

150 Milligram

Stopped :

CONTIN

Glyceryl Trinitrate (Other drug)

Reason:

10 Milligram

Daily

Topical

Batch :

Cream

Started:

Started:

Started:

Stopped :

CONTIN

PUTRAN02 Page 4 of 146



Cases Count: 144

Case Number: 74228

Gender: M

Data Entry Date: 20/11/1991 **Weight (kg)**: 23

Hospitalisation: Age: 7Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

Information: Depression, crying, saying he wants to kill himself. tried to run in front of cars.

threatened to jump off roof.

Reaction:

Preferred Term Severity Report Description Treatment

Depression

Psychotic disorder Suicide attempt

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 20 Milligram Daily Oral

Batch: **Started**: 14/07/1991 **Stopped**: 04/11/1991

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Cases Count: 144

Case Number: 92719

Gender: M

Data Entry Date: 03/05/1994

Weight (kg): 21

Hospitalisation:

Onset Date: 30/09/1992

Age: 8Y

DOB:

Outcome: Causality: Causality possible

Not yet recovered

Information: the dosage stop date is not necessarily accurate but indicates that stoppage occurred

sometime during the month.

Reaction:

Preferred Term Severity **Report Description Treatment**

Optic neuritis Severe Acute bilateral diag. nov

1993

Optic atrophy

Medicine details:

Ritalin (Suspected) Reason:

Tablet 10 Milligram Daily Oral

Started: 07/06/1992 Batch: Stopped: 28/10/1992

Laboratory Investigations:

Type Range Details Date Tested Result

Other data Vision (currently 3/60 I eye and 1/60 r

eye) & ngus of optic atrophy.

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Cases Count: 144

Case Number: 95597

Gender: F

Data Entry Date: 02/09/1994 **Weight (kg)**: 21

Hospitalisation: Age: 07Y

Onset Date: 29/08/1994 **DOB**:

Outcome : Causality : Causality possible

Death

Information: Patient died on the 29/8/94. she had two general anaesthetics in the month prior to her

death. the first was approx. four weeks before she died, the other gerneral anaesthetic was given approx. one week before she died. the day after each of those anaesthetics she had protracted vomiting but had recovered by the end of the day. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the

month.

Reaction:

Preferred Term Severity Report Description Treatment

Sudden death

Medicine details:

Catapres (Suspected) Reason :

Tablet 225 Microgram Daily Oral

Batch: Started: 28/04/1994 Stopped:

Ritalin (Suspected) Reason :

25 Milligram Daily

Batch: Started: 01/12/1991 Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Other data Post mortem findings normal.

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Cases Count: 144

Case Number: 102717

Gender: F

Data Entry Date: 09/08/1995 **Weight (kg)**: 26

Hospitalisation: Age: 9Y

Onset Date: 02/05/1995 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information: the dosage start date is not necessarily accurate but indicates that start occurred

sometime during the month.

Reaction:

Preferred Term Severity Report Description Treatment

Oculogyric crisis Head and eyes rolling to Stopped night dose of ritalin.

right

Medicine details:

Ritalin (Suspected) Reason :

Tablet 2.5 Dose Unspec Daily Oral

Batch: Started: 01/10/1994 Stopped:

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Cases Count: 144

Case Number: 104753

Gender: M

Data Entry Date: 21/11/1995 **Weight (kg)**: 34

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

Information: the dosage start date is not necessarily accurate but indicates that start occurred

sometime during the month.

Reaction:

Preferred Term Severity Report Description Treatment

Decreased appetite
Weight decreased

Medicine details:

Ritalin (Suspected) Reason :

40 Milligram Daily

Batch: Started: 01/04/1995 **Stopped:** 18/11/1995

Tofranil (Suspected) Reason :

50 Milligram Daily

Batch: **Started**: 01/04/1995 **Stopped**:

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Cases Count: 144

Case Number : 106364

Gender: M

Data Entry Date: 09/02/1996 **Weight (kg)**: 22

Hospitalisation: Age: 5Y

Onset Date: 01/02/1996 **DOB**:

Outcome : Causality : Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dystonia

Medicine details:

Ritalin (Suspected) Reason :

5 Milligram Daily

Batch: Started: 01/02/1996 **Stopped:** 01/02/1996

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Cases Count: 144

Case Number: 114965

Gender: M

Data Entry Date: 04/02/1997 **Weight (kg)**: 24

Hospitalisation: Age: 5Y

Onset Date: 31/12/1996 **DOB**:

Outcome: Causality: Causality certain

Not yet recovered

Information: Reaction has recurred after rechallengement of ritalin. - the date of onset is not

necessarily accurate but indicates that onset occurred sometime during the month.

Reaction:

Preferred Term Severity Report Description Treatment

Pollakiuria

Medicine details:

Ritalin (Suspected) Reason :

Tablet 20 Milligram Daily Oral

Batch: Started: 14/11/1996 **Stopped:** 31/12/1996

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Cases Count: 144

Case Number: 116359

Gender: F

DOB:

Data Entry Date: 26/03/1997

Weight (kg):

Hospitalisation:

Outcome:

weight (kg)

Onset Date: 28/02/1997

Age: 72Y

1136t Date: 20/02/1007

Causality: Causality possible

Death

Information: Committee comment: include in annual fatality analysis

Reaction:

Preferred Term Severity Report Description Treatment

Nausea Severe

Renal failure acute

Sudden death

Vomiting Severe

Medicine details:

Ritalin (Suspected) Reason :

0

Batch: **Started**: 25/02/1997

Stopped: 3D

Amlodipine (Other drug) Reason: Essential benign hypertension

5 Milligram Daily

Batch: Started: 01/02/1997 Stopped:

Aspirin (Other drug) Reason :

150 Milligram Daily

roo wiiiigram Da

Started: 01/01/1995 **Stopped**:

Enalapril Maleate (Other drug) Reason : Essential benign hypertension

20 Milligram Daily

Batch: Started: 01/01/1996 Stopped:

Maxolon (Other drug) Reason : Nausea and vomiting

30 Milligram Daily

Batch: Started: 01/09/1996 Stopped:

Simvastatin (Other drug) Reason :

10 Milligram Daily

Batch: Started: 01/01/1995 Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

 Creatinine
 28/01/1997 5

 Creatinine
 15/02/1997 5

Urea 28/01/1997 15 - 20

Urea 15/02/1997 15

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Cases Count: 144

Case Number: 116969

Gender: M

Data Entry Date: 21/04/1997 **Weight (kg)**: 45

Hospitalisation : Age: 13Y

Onset Date: 30/03/1997 **DOB**:

Outcome : Causality : Causality possible

Unknown

Information: the dosage start date is not accurate but indicates that start occurred sometime during

the year.

Reaction:

Preferred Term Severity Report Description Treatment

Aggression Physical aggression

Agitation

Insomnia Diazepam iv, catapress dose

increased, ritalin stopped.

Medicine details:

Ritalin (Suspected) Reason :

Tablet 10 Milligram Daily Oral

Batch: **Started**: 29/03/1997 **Stopped**: 31/03/1997

Catapres (Other drug) Reason :

Tablet 150 Milligram Daily Oral

Batch: Started: 01/01/1995 Stopped:

Epilim (Other drug) Reason : Other&unspecified epilepsy

0

Batch: Started: Stopped:

Sabril (Other drug) Reason : Other&unspecified epilepsy

0

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 119128

Gender: M

Data Entry Date: 16/07/1997 **Weight (kg)**: 90

Hospitalisation: Age: 14Y

Onset Date: 04/07/1997 **DOB**:

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Angioedema Lump in throat
Oedema peripheral Swollen hands

Dizziness Dyspnoea Fatigue

Headache Phenergan

Medicine details:

Aurorix (Suspected) Reason :

75 Milligram Daily

Batch: Started: 04/07/1997 Stopped:

Ritalin (Suspected) Reason :

10 Milligram Daily

Batch: Started: 04/07/1997 Stopped:

Prednisolone (Other drug) Reason : Asthma

0

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 120273

Gender: M

Data Entry Date: 25/08/1997 **Weight (kg)**: 45

Hospitalisation: Age: 11Y

Onset Date: 31/01/1997 **DOB**:

Outcome : Causality : Causality possible

Not yet recovered

Information: Patient has a history of asthma. - the date of onset is not necessarily accurate but

indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime

during the month.

Reaction:

Preferred Term Severity Report Description Treatment

Erythema multiforme Erythema multiforme legs

and lower trunk.

Medicine details:

Becotide (Suspected) Reason : Asthma

4 Dose Unspec Daily

Batch: Started: 01/01/1997 Stopped:

Ritalin (Suspected) Reason :

15 Millilitre Daily

Batch: Started: 01/06/1995 Stopped:

PUTRAN02 Page 15 of 146



Cases Count: 144

Case Number: 120281

Gender: M

Data Entry Date: 26/08/1997

Weight (kg): 21

Hospitalisation:

Outcome:

Age: 6Y

Onset Date: 24/07/1997

DOB:

Causality: Causality certain

Recovered

Information: Patient rechallenged on smaller dose of ritalin last dose on 20/7/97. awoke 24/7/97 with

florrid almost urticarial rash over face and trunk. family history: mother's sister allergic to

seafood. patient as a baby had food sensitivity.

Reaction:

Preferred Term

Rash

Severity

Report Description

Treatment

Polaramine.

Medicine details:

Ritalin (Suspected)

Reason:

5 Milligram

Daily

Batch:

Started: 18/07/1997

Stopped: 20/07/1997

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Cases Count: 144

Gender: U

Case Number : 121575

Data Entry Date: 13/10/1997 Weight (kg):

Hospitalisation: Age: 9Y

Onset Date: 14/04/1997 **DOB**: 13/04/1988

Outcome : Causality : Causality possible

Not yet recovered

Information: Ritalin and clonidine were both ceased and reinstituted at a low dose. ritalin was titrated

back up to 35mg daily but was no longer effective. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Reaction:

Preferred Term Severity Report Description Treatment
Fatigue

Medicine details: Actrapid Hm (Interaction) Reason: Diabetes mellitus Injection 12 Unit Daily Subcutaneous Started: Batch: Stopped: **Protaphane (Interaction)** Reason: Diabetes mellitus Injection 2 Unit Daily Subcutaneous Batch : Stopped: Started : Ritalin (Interaction) Reason: Oral application 35 Milligram Oral Daily Batch: Started: 01/04/1996 Stopped: CONTIN Clonidine Hydrochloride (Other drug) Reason: 150 Microgram Daily Batch: Started: Stopped:

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Cases Count: 144

Case Number: 122309

Gender: F

Data Entry Date: 12/11/1997

Weight (kg):

Hospitalisation:

Age: 63Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Pseudolymphoma

		e d		

Deralin (Suspected) Reason: Anxiety neurosis

Tablet 120 Milligram Daily Oral

Batch: Started: 01/01/1993 **Stopped:** 31/01/1996

Deralin (Suspected) Reason : Anxiety neurosis

Tablet 240 Milligram Daily Oral

Batch: Started: 01/01/1989 **Stopped:** 31/01/1993

Melleril (Suspected) Reason :

Oral application 1 Dose Unspec Daily Oral

Batch: **Started**: **Stopped**: 31/01/1996

Ogen (Suspected) Reason :

0

Batch: Started: 01/01/1989 **Stopped:** 31/01/1996

Progesterone (Suspected) Reason:

0

Batch: Started: Stopped:

Prothiaden (Suspected) Reason :

Oral application 25 Milligram Daily Oral

Batch: Started: Stopped: 31/01/1996

Ritalin (Suspected) Reason :

0

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 123253

Gender: F

Data Entry Date: 10/12/1997

Weight (kg):

Hospitalisation:

Onset Date: 08/10/1997

Age: 67Y

Outcome:

DOB:

Causality: Causality possible

Death, maybe drug

Information: Patient died 12/10/97.

Reaction:

Preferred Term Severity **Report Description**

Treatment

Hallucination

Confusional state

Visual hallucinations

Ceased ritalin and changed to

morphine mix.

Medicine details:

Ciprofloxacin (Suspected)

Reason: Unspecified septicemia

Tablet

Batch:

1.5 Gram

Daily

Stopped: 08/10/1997

Coloxyl With Senna (Suspected)

Reason: Constipation

Tablet

4 Dose Unspec Daily

Oral

Oral

Batch:

Started: 29/09/1997

Started: 29/09/1997

Stopped: 08/10/1997

Dothiepin Hydrochloride (Suspected)

Reason:

Daily

Batch:

Started: 19/09/1997

Stopped: 08/10/1997

Gastrogel (Suspected)

Reason: Nausea and vomiting 3 Dose Unspec Daily

Batch:

Started: 06/10/1997

Stopped: 09/10/1997

Ms Contin (Suspected)

Reason: Pain

75 Milligram

Tablet

40 Milligram

Daily

Daily

Oral

Batch:

Started: 29/09/1997

Stopped: 08/10/1997

Panadol (Suspected) Oral application

Reason: Pain

Oral

Batch:

Started: 30/09/1997

Stopped: 08/10/1997

Ritalin (Suspected)

Reason:

4 Gram

Tablet

10 Milligram

Daily

Oral Stopped: 08/10/1997

Batch: Slow-k (Suspected)

Reason:

2 Dose Unspec Daily

Batch:

Started: 29/09/1997

Started: 07/10/1997

Stopped: 08/10/1997

Xylocaine Jelly (Suspected)

Reason: Otr&unspec oral soft tissu dis

Gel

3 Dose Unspec Daily

Topical

Batch:

Started: 06/10/1997

Stopped: 09/10/1997

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Medicine details:

Dexamethasone (Other drug) Reason: Nausea and vomiting

Oral application 2 Milligram Daily Oral

Batch: **Started**: 03/10/1997 **Stopped**: 10/10/1997

Maxolon (Other drug) Reason : Nausea and vomiting

Tablet 40 Milligram Daily Oral

Batch: **Started**: 02/10/1997 **Stopped**: 12/10/1997

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Cases Count: 144

Case Number: 124338

Gender: M

Data Entry Date: 22/01/1998 Weight (kg): 29

Hospitalisation: Age: 9Y

DOB: Onset Date:

Causality: Causality probable Outcome:

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment** Hallucination Tactile hallucinations,

visual hallucinations.

Ceased ritalin.

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet Oral 30 Milligram Daily

Stopped: 05/12/1997 Batch: Started: 24/07/1997

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Cases Count: 144

Case Number: 125581 Gender: M

Data Entry Date: 06/03/1998 Weight (kg):

Hospitalisation: Age: 15Y

Onset Date: 20/02/1998 **DOB**:

Outcome: Causality: Causality possible

Recovered

Information: Patient suffers from attention deficit disorder, autism and personality disorder and

behavioural problems.

Reaction:

Preferred Term Severity Report Description Treatment

Otitis media Right otitis media

Pyrexia Temp up to 39 degrees c.

Ataxia Zoloft reduced to 50mg/d and

ritalin reduced to 40mg/d.

Diarrhoea
Headache
Pharyngitis
Photophobia
Viral infection

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 50 Milligram Daily Oral

Batch: Started: Stopped:

Zoloft (Suspected) Reason : Depression

Tablet 100 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 131913

Gender: M

Data Entry Date: 09/10/1998 **Weight (kg)**: 30

Hospitalisation: Admitted to hospital **Age**: 6Y

Onset Date : DOB :

Outcome: Causality: Causality certain

Unknown

Information: When ritalin was increased to 2 tabs patient experienced symptoms drug was stopped.

trial of ritlain half tab given, then up to two tabs daily, patient again experienced same

symptoms.

Reaction:

Preferred Term Severity Report Description Treatment

Dyspnoea

Tachycardia

Medicine details:

Ritalin (Suspected) Reason :

Tablet 2 Dose Unspec 1 time Oral

Batch : Started : Stopped :

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Cases Count: 144

Case Number: 132576

Gender: F

Data Entry Date: 30/10/1998 **Weight (kg)**: 20

Hospitalisation: Age: 3Y

Onset Date: 22/10/1998 **DOB**:

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dyskinesia Orobuccal Ceased ritalin.

dyskinesia/lip-smack.tongue

protrusions

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 15 Milligram Daily Oral

Batch: **Started**: 22/10/1998 **Stopped**: 22/10/1998

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Cases Count: 144

Case Number: 133611

Gender: M

Data Entry Date: 24/11/1998 **Weight (kg)**: 23

Hospitalisation: Age: 6Y

Onset Date: 17/11/1998 **DOB**:

Outcome : Causality : Causality probable

Recovered

Information: Pt reacts to red and green food dyes. adverse reaction occurred after 2nd dose. the

dosage start date is not necessarily accurate but indicates that start occurred sometime

during the month.

Reaction:

Preferred Term Severity Report Description Treatment

Fatigue Severe Extreme tiredness

Cold sweat Somnolence

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Injection 2.5 Dose Unspec Daily Intramuscular

Batch: Started: 01/08/1998 Stopped:

Clonidine Hydrochloride (Other drug) Reason : Behavior disorders of childhood

100 Microgram Daily

Batch: Started: 17/11/1998 Stopped:

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Cases Count: 144

Case Number: 135266 Gender: M

Data Entry Date: 20/01/1999 Weight (kg):

Hospitalisation: Age: AC

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: Tablets dispensed from a webster pack do not appear to work in this child. yet those

dispensed from a blister pack do.

Reaction:

Preferred Term Severity Report Description Treatment

Drug ineffective Loss of efficacy after 14

days to a month.

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood
Tablet 0 Oral

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 136672

Data Entry Date: 26/02/1999 Weight (kg):

Hospitalisation: Age: A2

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information: The shakes were only present on sunday morning which were attributed by the parents

to over-indulgence the previous night (alcohol). the patient has continued to take ritalin

and feels much better.

Reaction:

Preferred Term Severity Report Description Treatment

Tremor

Medicine details:

Alcohol (Suspected) Reason :

0

Batch: Started: Stopped:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 50 Milligram Daily Oral

Batch: Stopped:

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Cases Count: 144

Case Number: 137983

Data Entry Date: 30/03/1999 Weight (kg):

Hospitalisation: Age: 11Y

Onset Date: 31/07/1995 **DOB**:

Outcome : Causality : Causality possible

Recovered

Information: Has now gone back onto medication and obsessive compulsive disorder has returned. -

the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month, the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month, the dosage start date is not necessarily

accurate but indicates that start occurred sometime during the month.

Reaction:

Preferred Term Severity Report Description Treatment

Neurosis Obsessive compulsive Ceased all medication

disorde3r in structered

form

Medicine details:

Catapres (Suspected) Reason :

1 Dose Unspec Daily

Batch: **Started**: 01/07/1995 **Stopped**:

Ritalin (Suspected) Reason :

1 Dose Unspec Daily

Batch: Started: 01/07/1995 Stopped:

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Cases Count: 144

Case Number: 140184

Gender: F

Data Entry Date: 02/06/1999

Weight (kg):

Hospitalisation:

Age: 11Y

Onset Date: 31/05/1999

DOB: 28/02/1988

Outcome:

Causality: Causality possible

Unknown

Information: Please see original report for details of other drugs - anafranil. - the date of onset is not

necessarily accurate but indicates that onset occurred sometime during the month.

Reaction:

Preferred Term

Severity

Report Description

Daily

Treatment

Drug ineffective

Loss of behavioural control

Medicine details:

Ritalin (Suspected)

Reason: Behavior disorders of childhood

Batch:

Tablet

Started:

0

Stopped:

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Cases Count: 144

Case Number: 140212

Gender: M

Data Entry Date: 02/06/1999 **Weight (kg)**: 59

Hospitalisation: Age: 13Y

Onset Date: 08/05/1999 **DOB**:

Outcome: Causality: Causality probable

Recovered

Information: Patient remained nauseous and weak. stayed in bed for the next 3 days.

Reaction:

Preferred Term Severity Report Description Treatment

Aggression Agressive and angry.

Amnesia Amnesia for 1 hour.

Somnolence Drowsy and quiet after one

hour.

Nausea Felt nauseous all week.
Influenza like illness Flu-like symptoms.
Crying Terrified, crying.

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 0.5 Dose Unspec Daily Oral

Batch: **Started**: 08/05/1999 **Stopped**: 08/05/1999

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Cases Count: 144

Case Number: 140311 Gender: M

Data Entry Date: 07/06/1999 Weight (kg):

Hospitalisation: Age: 10Y

Onset Date: 17/05/1999 **DOB**: 20/04/1989

Outcome : Causality : Causality possible

Recovered

Information: Patient has been on ritalin for approxomately one year without problems. started a new

pack from a different batch and experienced symptoms. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Reaction:

Preferred Term Severity Report Description Treatment
Insomnia

Mania

Tachycardia

Medicine details	:					
Ritalin (Suspected)		Reason: Behavior disorders of childhood				
Tablet	10 Mil	ligram	Daily		Oral	
Batch :	Started : 01/06/1998			Stopped :		
Catapres (Other drug)		Re	ason :			
	0					
Batch :	Started :			Stopped :		
Clonidine Hydrochloride (Otl	her drug)	Reason :				
	0					
Batch :	Started :			Stopped :		

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Cases Count: 144

Case Number: 140625

Gender: F

Data Entry Date: 16/06/1999

Weight (kg):

Hospitalisation:

Age: 10Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Alopecia

Tablet

Lge bald patch on crown & frontal section of head.

Medicine details:

Ritalin (Suspected)

Reason:

55 Milligram

Daily

Oral

Batch:

Started:

Stopped:

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Cases Count: 144

Case Number: 140767

Data Entry Date: 21/06/1999 Weight (kg):

Hospitalisation : Age :

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Tremor Shaking uncontrollably

Aggression Neurosis

Medicine details:

Ritalin (Suspected) Reason :

Tablet 0 Oral

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 140877 Gender: U

Data Entry Date: 24/06/1999 Weight (kg):

Hospitalisation : Age :

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Tooth discolouration

Medicine details:

Ritalin (Suspected) Reason :

Tablet 0 Daily Oral

Batch: Started: Stopped:

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Cases Count: 144

Oral

Case Number: 140972

Data Entry Date: 29/06/1999 Weight (kg):

Hospitalisation : Age :

Onset Date : DOB :

Outcome : Causality : Causality possible

Daily

Unknown

Information:

Reaction:

Tablet

Preferred Term Severity Report Description Treatment

Weight decreased

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

0

Batch: Started: Stopped:

PUTRAN02 Page 35 of 146



Cases Count: 144

Case Number: 140974

Gender: M

Data Entry Date: 29/06/1999

Weight (kg):

Hospitalisation:

Age: 04Y

Onset Date: 31/05/1999

DOB: 22/07/1994

Outcome:

Causality: Causality possible

Unknown

Information:

The patient has a history of low muscle tone and chronic tonsillitis and upper respiratory

tract infections. - the date of onset is not necessarily accurate but indicates that onset

occurred sometime during the month.

Reaction:

Preferred Term

Abdominal pain

Vomiting

Severity

Report Description

Treatment

Gagging/dry retching and wanting to vomit.

Patient experienced a sore

stomach.

Nervousness

Patient was irritable (easily

Ritalin discontinued.

cried).

Decreased appetite

Headache

Medicine details:

Ritalin (Suspected)

Reason:

Daily

Tablet Batch:

Started: 10/05/1999

Stopped: 15/05/1999

Oral

PUTRAN02 Page 36 of 146



Cases Count: 144

Gender: M

Case Number: 142567

Data Entry Date: 11/08/1999 Weight (kg):

Hospitalisation: Age: 16Y

Onset Date: 31/12/1999 DOB: 12/11/1982

Outcome: Causality: Causality possible

Unknown

Information: Symptoms occurred while patient was receiving ritalin therapy. - the date of onset is not

accurate but indicates that onset occurred sometime during the year.

Reaction:

Preferred Term Severity Report Description Treatment

Neurosis

Medicine details:

Ritalin (Suspected) Reason : Other atyp forms schizophrenia

Tablet 0 Daily Oral

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 142590

Gender: M

Data Entry Date: 11/08/1999

Weight (kg):

Hospitalisation:

Age: 5Y

Onset Date: 31/07/1999

DOB: 06/10/1993

Outcome:

Causality: Causality possible

Unknown

Information:

Patient history of: lactose intolerance. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not

necessarily accurate but indicates that start occurred sometime during the month.

Reaction:

Preferred Term Severity

Report Description

Treatment

Diarrhoea Severe

Loose everyday and pale in

colour

Medicine details:

Ritalin (Suspected)

Reason: Behavior disorders of childhood

Tablet

5 Milligram

Daily

Oral Stopped :

Batch :

Started: 01/06/1999

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Cases Count: 144

Case Number: 142958

Gender: F

Data Entry Date: 24/08/1999 **Weight (kg)**: 40

Hospitalisation: Age: 10Y

Onset Date: 31/05/1999 **DOB**:

Outcome : Causality : Causality possible

Recovered

Information: - the date of onset is not necessarily accurate but indicates that onset occurred

sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates

that start occurred sometime during the year.

Reaction:

Preferred Term Severity Report Description Treatment

Alopecia Ritalin therapy ceased.

Medicine details:

Ritalin (Suspected) Reason :

0

Batch: Started: 01/01/1994 Stopped:

Catapres (Other drug) Reason :

0

Batch: **Started**: 01/01/1996 **Stopped**:

PUTRAN02 Page 39 of 146



Cases Count: 144

Gender: M

Case Number: 143438

Data Entry Date: 03/09/1999 Weight (kg):

Hospitalisation: Age: 14Y

Onset Date: 31/07/1999 **DOB**: 12/11/1984

Outcome: Causality: Causality certain

Unknown

Information: Ritalin given for attention deficit disorder, reaction has been occurring over the last 4-6

weeks. the patient does not mix socially, which is a problem at school. the patient has also stopped seeing his counsellor over the last month. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime

during the month.

Reaction:

Preferred Term Severity Report Description Treatment

Depression Feels depressed about an hour after taking ritalin

Medicine details:

Ritalin (Suspected) Reason :

Tablet 35 Milligram Daily Oral

Batch: **Started**: 01/09/1998 **Stopped**:

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Cases Count: 144

Case Number: 143680

Data Entry Date: 13/09/1999 Weight (kg):

Hospitalisation: Age: 11Y

Onset Date: 20/08/1999 **DOB**:

Outcome: Causality: Causality possible

Recovered

Information: Ritalin given for attention deficit hyperactivity disorder. ritalin batch no: lot b 056700.

Reaction:

Preferred Term Severity Report Description Treatment

Hyperkinesia Felt compelled to move his

hands continually

Hyperkinesia Felt compelled to move his

head from side to side.

Drug ineffective Started behaving as if The reaction stopped with use

ritalin was not working of catapres and discontinuation

Gender: M

of ritalin.

Medicine details:

Ritalin (Suspected) Reason :

Tablet 30 Milligram Daily Oral

Batch: LOTB056700 **Started**: 30/03/1995 **Stopped**: 25/08/1999

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Cases Count: 144

Case Number : 143687

Gender: F

Data Entry Date: 13/09/1999

Weight (kg):

Hospitalisation:

Age: 8Y

Onset Date: 31/08/1999 DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Ritalin given for attention deficit hyperactivity disorder. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime

during the month.

Reaction:

Preferred Term Severity Report Description

Treatment

Alopecia

Medicine details:

Ritalin (Suspected) Reason :

Tablet 30 Milligram Daily Oral

Batch: Started: 01/05/1999 Stopped: CONTIN

PUTRAN02 Page 42 of 146



Cases Count: 144

Case Number: 143689

Data Entry Date: 13/09/1999 Weight (kg):

Hospitalisation : Age :

Onset Date: 31/12/1996 **DOB**:

Outcome: Causality: Causality possible

Unknown

Information: Ritalin given for attention deficit hyperactivity disorder. reaction worsened since the

dosage was increased. it looks like the child has "chewed the inside of his mouth" and has lesions of the buccal mucosa. - the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but

indicates that start occurred sometime during the year.

Reaction:

Preferred Term Severity Report Description Treatment

Gingival hyperplasia Chronic swelling in the

mouth

Medicine details:

Ritalin (Suspected) Reason :

Tablet 50 Milligram Daily Oral

Batch: Started: 01/01/1996 Stopped: CONTIN

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Tablet

Public Case Detail

Cases Count: 144

Case Number: 144534

Gender: M

Oral

Data Entry Date: 11/10/1999 Weight (kg):

Hospitalisation: Age: 12Y

Onset Date : DOB : 11/01/1987

Outcome: Causality: Causality possible

Unknown

Information: the dosage start date is not accurate but indicates that start occurred sometime during

the year.

Reaction:

Preferred Term Severity Report Description Treatment

Gingival hyperplasia

Medicine details: **Bricanyl (Suspected)** Reason: Inhalation 0 Inhalation Batch: Started: Stopped: Pulmicort (Suspected) Reason: Inhalation 800 Microgram Daily Inhalation Batch: Stopped: Started: Reason: Behavior disorders of childhood Ritalin (Suspected)

Daily

Batch: Started: 01/01/1996 Stopped: CONTIN

50 Milligram

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Cases Count: 144

Case Number: 145127 Gender: M

Data Entry Date: 27/10/1999 Weight (kg):

Hospitalisation: Age: 15Y

Onset Date: 20/10/1999 **DOB**:

Outcome : Causality : Causality possible

Unknown

Information: Patient took 8 at one time and then 2 to 3 tabs every couple of hours. total of 20 x 10mg

tablets taken.

Reaction:

Preferred Term Severity Report Description Treatment

Suicide attempt Overdose of 20 x 10 mg.

Medicine details:

Ritalin (Suspected) Reason :

Tablet 200 Milligram Total Oral

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 145130

Gender: F

Data Entry Date: 27/10/1999

Weight (kg):

Hospitalisation:

Onset Date: 31/12/1999

DOB: 09/08/1949

Age: 50Y

Outcome:

Causality: Causality possible

Recovered

Information: Ritalin dose was reduced but patient continued having adverse effects. patient recovered and had no reaction upon readministration. - the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Reaction:

Preferred Term Severity **Report Description Treatment**

Headaches Headache

Hyperhidrosis Pouring sweat when dose

increased to 40mg daily.

Paranoia `a touch paranoid'

Nervousness `nervy'

Depression 'weepiness (crying)'

Medicine details:

Ritalin (Suspected) Reason: Cataplexy&narcolepsy brain dis

Tablet 35 Milligram Oral Daily

CONTIN Batch: Started: 01/01/1999 Stopped:

Methotrexate (Other drug) Reason:

> 10 Milligram Daily

Batch: Started: Stopped:

Pepcidine (Other drug) Reason:

> 40 Milligram Daily

Batch: Started: Stopped:

Prepulsid Forte (Other drug) Reason:

1 Dose Unspec Total

Batch: Started: Stopped:

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Cases Count: 144

Gender: M

Case Number: 147205

Data Entry Date: 20/12/1999 Weight (kg):

Hospitalisation: Age: 5Y

Onset Date: 17/11/1999 DOB: 24/10/1994

Outcome : Causality : Causality possible

Not yet recovered

Information: the dosage start date is not necessarily accurate but indicates that start occurred

sometime during the month.

Reaction:

Infection

Preferred Term Severity Report Description Treatment

Rash Scaley scaby thing on Antibiotics

head. pt scratching the

area

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood
Tablet 5 Milligram Daily Oral

Batch: Started: 01/09/1999 Stopped: CONTIN

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Cases Count: 144

Case Number: 147288

Gender: F

Data Entry Date: 20/12/1999 Weight (kg):

Hospitalisation: Age: 37Y

Onset Date: 23/11/1999 **DOB**: 27/07/1962

Outcome: Causality: Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Pancreatitis			

Medicine details: Ritalin (Suspected) Reason: Tablet 10 Milligram Oral Daily Batch: Started: 09/11/1999 Stopped: Aropax (Other drug) Reason: 0 Batch: Stopped: Started: **Entocort (Other drug)** Reason: 0 Batch: Started: Stopped: Kapanol (Other drug) Reason: 0 Stopped: Batch: Started:

Laboratory Investigations:

Type Range Date Tested Result Details

Amylase Raised amylase.

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Cases Count: 144

Case Number: 148166 Gender: M

Data Entry Date: 17/01/2000 Weight (kg):

Hospitalisation: Age: 9Y

Onset Date: 05/01/2000 **DOB**:

Outcome : Causality : Causality possible

Unknown

Information:

R	е	a	C	ti	0	n	:
•	_	u	•	••	•		•

Preferred Term Severity Report Description Treatment

Apathy Withdrawn and unusual

behaviour

Withdrawal syndrome

_	-			-								
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ш	w	_	. 1				_		-	_	 •	
		•	v		•		$\overline{}$	v	\mathbf{v}	··	•	-

Clonidine Hydrochloride (Suspected) Reason :

0

Batch: Started: Stopped:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 100 Milligram Daily Oral

Batch: Started: Stopped:

Tofranil (Suspected) Reason :

0

Batch: Started: Stopped:

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Cases Count: 144

Case Number : 150682

Gender: U

Data Entry Date: 22/03/2000

Weight (kg):

Hospitalisation:

Onset Date: 31/12/1999

Age: 13Y

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

This reaction has been happening for a couple of months. patient has been on ritalin treatment for one year. - the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates

that start occurred sometime during the year.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Dysgeusia

Soft drink & general food

tastes of garlic.

Medicine details:

Ritalin (Suspected)

Reason:

Oral

Tablet

10 Milligram

Daily

Stopped: CONTIN

Batch :

Started: 01/01/1999

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Cases Count: 144

Case Number: 151227 Gender: M

Data Entry Date: 03/04/2000 Weight (kg):

Hospitalisation: Age: 6Y

Onset Date : DOB : 25/08/1993

Outcome: Causality: Causality certain

Not yet recovered

Information: Patient has experienced symptoms each night since commencing treatment with ritalin.

the dosage start date is not necessarily accurate but indicates that start occurred

sometime during the month.

Reaction:

Preferred Term Severity Report Description Treatment

Hyperhidrosis

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 10 Milligram Daily Oral

Batch: Started: 01/02/2000 Stopped: CONTIN

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Cases Count: 144

Case Number: 151240

Gender: M

Data Entry Date: 30/03/2000

Weight (kg):

Hospitalisation:

Onset Date: 29/02/2000

DOB: 19/04/1994

Age: 5Y

Outcome:

Causality: Causality possible

Unknown

Information: the dosage start date is not necessarily accurate but indicates that start occurred

sometime during the month.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Drug ineffective

Medicine details:

Ceclor (Interaction)

Reason:

500 Milligram

15 Milligram

Oral

Batch:

Solution

Tablet

Started: 29/02/2000

Stopped:

Ritalin (Interaction)

Reason:

Daily

Daily

Oral

Batch:

Started: 01/12/1999

Stopped:

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Cases Count: 144

Case Number: 152295

Data Entry Date: 01/05/2000 Weight (kg):

Hospitalisation: Age: 15Y

Onset Date: 31/12/1997 DOB: 25/03/1985

Outcome: Causality: Causality certain

Unknown

Information: Patient experiences symptoms afer every dose of ritalin. - the date of onset is not

necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime

during the month.

Reaction:

Preferred Term Severity Report Description Treatment

Palpitations Ritalin dose was reduced

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 30 Milligram Daily Oral

Batch: **Started**: 01/12/1997 **Stopped**: 17/04/2000

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Cases Count: 144

Case Number: 152528 Gender: F

Data Entry Date: 10/05/2000 Weight (kg):

Hospitalisation : Age :

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: the dosage start date is not necessarily accurate but indicates that start occurred

sometime during the month.

Reaction:

Preferred TermSeverityReport DescriptionTreatmentAbdominal painStomach painsCeased ritalin

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 0 Oral

Batch: Started: 01/02/2000 Stopped:

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Cases Count: 144

Case Number: 153009 Gender: M

Data Entry Date: 24/05/2000 Weight (kg):

Hospitalisation: Age: 4Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: the dosage start date is not necessarily accurate but indicates that start occurred

sometime during the month.

Reaction:

Preferred Term Severity Report Description Treatment

Weight decreased Weight loss between

11/99-5/2000

Medicine details:

Ritalin (Suspected) Reason : Behavior disorders of childhood

Tablet 10 Milligram Daily Oral

Batch: **Started**: 01/11/1999 **Stopped**: CONTIN

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Cases Count: 144

Gender: M

Case Number: 153411

Data Entry Date: 05/06/2000 Weight (kg):

Hospitalisation: Age: 07Y

Onset Date: 23/05/2000 DOB: 23/03/1993

Outcome : Causality : Causality possible

Unknown

Information: Patient also taking beclomethasone and amitriptyline. the patient takes 3/4 of a tablet

three times daily. the dose has been reduced to 1/2 tablet three times daily. the adverse event was described by the patient as rolling the tongue and eating when there is no food in the mouth. the dosage start date is not accurate but indicates that start occurred

sometime during the year.

Reaction:

Preferred Term Severity Report Description Treatment

Tardive dyskinesia

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 22.5 Milligram Daily Oral

Batch: Started: 01/01/1998 Stopped: CONTIN

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Cases Count: 144

Case Number: 155100

Gender: M

Data Entry Date: 17/07/2000

Weight (kg):

Hospitalisation: Admitted to hospital

Age: 17Y

Onset Date: 02/07/2000

DOB: 14/05/1983

Outcome:

Causality: Causality possible

Recovered

Information: the dosage start date is not necessarily accurate but indicates that start occurred

sometime during the month.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Hypertension

Blood pressure measured to be 190/115 mmhg.

Dizziness

Medicine details:

Ritalin (Suspected)

Reason:

Reason:

Daily

Oral

Tablet Batch:

Started: 01/06/2000

Stopped: 03/07/2000

Sleep Ease (Suspected)

0

60 Milligram

Oral

Oral application Batch:

Started:

Stopped:

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Cases Count: 144

Case Number: 155468

Gender: F

Data Entry Date: 24/07/2000

Weight (kg):

Hospitalisation:

Age: 12Y

Onset Date: 31/12/2000

DOB:

Outcome:

Causality: Causality possible

Unknown

Information: - the date of onset is not accurate but indicates that onset occurred sometime during the

year. the dosage start date is not accurate but indicates that start occurred sometime

during the year.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Decreased appetite

Medicine details:

Reason: Behavior disorders of childhood

Stopped:

Tablet

50 Milligram

Daily

Oral

CONTIN

Ritalin (Suspected)

Batch:

Started: 01/01/1999

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Cases Count: 144

Case Number: 155469 Gender: M

Data Entry Date: 24/07/2000 Weight (kg):

Hospitalisation: Age: 9Y

Onset Date: 31/12/2000 **DOB**:

Outcome : Causality : Causality possible

Unknown

Information: - the date of onset is not accurate but indicates that onset occurred sometime during the

year. the dosage start date is not accurate but indicates that start occurred sometime

during the year.

Reaction:

Preferred Term Severity Report Description Treatment

Decreased appetite

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 35 Milligram Daily Oral

Batch: Started: 01/01/1999 Stopped: CONTIN

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Cases Count: 144

Case Number : 155499

Gender: M

Data Entry Date: 26/07/2000

Weight (kg):

Hospitalisation:

Age: 19Y

Onset Date: 31/07/2000

DOB: 29/09/1980

Outcome:

Causality: Causality possible

Unknown

Information:

The patient recently purchased a new pack of ritalin from a different pharmacy than usual. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start

occurred sometime during the year.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Anxiety

Depression

Nervousness

Medicine details:

Ritalin (Suspected)

Reason:

30 Milligram

Daily

Oral

Batch:

Tablet

Started: 01/01/1998

Stopped:

CONTIN

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Cases Count: 144

Case Number: 156659

Data Entry Date: 18/08/2000 Weight (kg):

Hospitalisation : Age :

Onset Date: 19/06/2000 **DOB**:

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Alopecia

Medicine details:

Ritalin (Suspected) Reason :

Tablet 10 Milligram Daily Oral

Batch: Started: 19/06/2000 Stopped:

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Cases Count: 144

Case Number : 156888

Gender: M

Data Entry Date: 23/08/2000

Weight (kg):

Hospitalisation:

Age: 13Y

Onset Date :

DOB: 08/05/1987

Outcome:

Causality: Causality possible

Unknown

Information: Patient has unstable asthma.

Severity

Reaction:

Preferred Term

Report Description

Treatment

Agitation

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 25 Milligram Daily Oral

Batch: Started: Stopped:

Ventolin (Suspected) Reason :

0

Batch: Started: Stopped:

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Cases Count: 144

Case Number : 157565

Gender: M

Data Entry Date: 07/09/2000

Weight (kg):

Hospitalisation:

Age: 12Y

Onset Date :

DOB: 29/04/1988

Outcome:

Causality: Causality possible

Unknown

Information:

The community pharmacy is using methylphenidate capsules, compounded by the pharmacist and assumed to have sustained released properties - extemporaneous preparation. the dosage start date is not accurate but indicates that start occurred

sometime during the year.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Neurosis

Patient went into a "trance"

like state.

Thinking abnormal

Medicine details:

Ritalin (Suspected)

Reason:

Capsule

20 Milligram

Daily

Oral

Batch :

Started: 01/01/1991

Stopped:

CONTIN

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Cases Count: 144

Case Number: 157696

Gender: M

Data Entry Date: 07/09/2000

Weight (kg):

Hospitalisation:

Age: 11Y

Onset Date: 23/08/2000

DOB: 23/03/1989

Outcome:

Causality: Causality possible

Recovered

Information: The dose start and stop dates for ritalin are not necessarily accurate but indicate that

the drug was started and stopped sometime in the months stated.

Reaction:

Preferred Term Aplastic anaemia Severity

Report Description

Treatment

Treated by bone marrow transplantation in nov 2000.

Pancytopenia

Medicine details:

Ritalin (Suspected)

Reason:

10 Milligram

Daily

Oral

Batch:

Tablet

Started: 01/04/1998

Stopped: 28/08/2000

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Cases Count: 144

Case Number: 167739

Gender: M

Data Entry Date: 20/08/2001

Weight (kg):

Hospitalisation: Admitted to hospital

Age: 56Y

Onset Date: 10/08/2001

DOB: 08/09/1945

Outcome:

Causality: Causality possible

Recovered

Information: Patient has pre-existing arrhythmias. consumed wine, cheese and a banana.

Reaction:

Preferred Term Severity

Report Description

Treatment

Chest pain

Severe

Severe chest pain.

Patient was hospitalised. treated with morphine.

Myocardial infarction

Medicine details:

Electrocardiogram abnormal

Alcohol (Suspected)

Reason:

Batch:

Started:

Stopped:

Ritalin (Suspected)

Reason: Behavior disorders of childhood

Tablet

Electrocardiography

10 Milligram Daily

0

Oral

Batch:

Started:

L TERM

Stopped: 10/08/2001

06Y

Laboratory Investigations:

Range

Date Tested Result

Details

Ecg showed high qrs, probable inferior

Type

infarct and st elevation.

PUTRAN02



Cases Count: 144

Case Number : 174735

Gender: F

Data Entry Date: 22/04/2002 Weight (kg):

Hospitalisation: Age: 07Y

Onset Date: 07/03/2002 DOB:

Outcome : Causality : Causality possible

Not yet recovered

Information: Developed a tic on 7 march 2002, 5 months after commencing riatlin. initially it involved

both arms, then became more complex with hands, fingers, and wrists, the neck, head and hips. ritalin was ceased on 9 march 2002. there had been slight improvement since cessation, with movements of head, arm, neck and legs subsiding but the movements

were still present.

Reaction:

Preferred Term Severity Report Description Treatment

Dyskinesia

Muscle twitching

Nightmare

Rash

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 10 Milligram Daily Oral

Batch: **Started**: 01/10/2001 **Stopped**: 09/03/2002

Efalex (Other drug) Reason :

0

Batch: Started: Stopped:

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Cases Count: 144

Case Number : 183683

Gender: M

Data Entry Date: 04/03/2003

Weight (kg): 35

Hospitalisation:

Age:

Onset Date :

DOB: 16/10/1997

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Hallucination

Hallucinations

Daily

Ritalin was discontinued.

Medicine details:

Ritalin (Suspected)

Batch:

Reason: Behavior disorders of childhood

Capsule 40 Milligram

Started:

Stopped :

Oral

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Hospitalisation:

Public Case Detail

Cases Count: 144

none required effect passed

none required effect passed

with time

with time

Case Number: 185405

Gender: M

Data Entry Date: 05/05/2003 Weight (kg): 35

Age:

Onset Date: 29/04/2003 **DOB**: 13/10/1989

Outcome: Causality: Causality certain

Recovered

Information: Coded certain because of rechallenge.

Required Specialist

Reaction:

Diarrhoea

Preferred Term Severity Report Description Treatment

Consultation diarrhoea within one hour

of oral dose -effect lasted

4-6 hrs.

Given 48 hrs off traeatment

and single dose repeated

with same effect

Acute nausea and

Nausea Required Specialist

Consultation

Acute nausea and

diarrhoea within one hour

of oral dose -effect lasted

4-6 hrs.

Given 48 hrs off traeatment

and single dose repeated

with same effect

Medicine details:

Ritalin LA (Suspected) Reason: Behavior disorders of childhood

Capsule, modified release 30 Milligram 1 time Oral

Batch: **Started**: 28/04/2003 **Stopped**: 04/05/2003

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Cases Count: 144

Case Number: 186035

Gender: M

Data Entry Date: 19/05/2003 **Weight (kg)**: 20

Hospitalisation : Age :

Onset Date: 09/05/2003 **DOB**: 29/03/1995

Outcome: 20/05/2003 Causality: Causality probable

Recovered

Information: Symptoms seem to increase with each dose, ceased after 4 doses.

Reaction: **Preferred Term Treatment** Severity **Report Description** Abdominal pain Required Visit to Headache, nausea, Doctor abdominal pain, pale face, drowsness Required Visit to Headache Headache, nausea, abdominal pain, pale face, Doctor drowsness Required Visit to Nausea Headache, nausea, **Doctor** abdominal pain, pale face, drowsness Pallor Required Visit to Headache, nausea, Doctor abdominal pain, pale face, drowsness Headache, nausea, Somnolence Required Visit to abdominal pain, pale face, Doctor drowsness

Medicine details	:					
Ritalin (Suspected)		Rea	ason :			
Tablet		10 Milligram	Daily		Oral	
Batch :	Started :			Stopped :		
Ritalin (Suspected) Reason :						
Capsule		15 Milligram	Daily		Oral	
Batch :	Started :			Stopped :		
Catapres (Other drug) Reason :						
Tablet		1 Dose Unspe	c Daily		Oral	
Batch :	Started :			Stopped :		

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Cases Count: 144

Case Number: 189644

Gender: M

Data Entry Date: 18/08/2003 **Weight (kg)**: 30

Hospitalisation : Age :

Onset Date: 10/08/2003 DOB: 06/01/1998

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dyskinesia Required Visit to Tourettes type diskynesias

Doctor - hunching shoulders, shooting out arm, opening

eyes

wide, twitching and blinking hard. TV exacerbates it.

Medicine details:

Ritalin (Suspected) Reason : Behavior disorders of childhood

0.5 Dose Unspec Daily Oral

Batch: **Started**: 06/08/2003 **Stopped**: 10/08/2003

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Cases Count: 144

Case Number: 190321

Gender: F

Data Entry Date: 08/09/2003

Weight (kg): 67

Hospitalisation:

Age: 14Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information: No lab test provided. Other drugs used: Zoloft, Risperidone, Seroquel.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Androgens increased

Androgen levels high, tremors, blurred vision,

lack of effect, eye twitches.

Drug ineffective

Muscle twitching

Tremor

Vision blurred

Medicine details:

Ritalin (Suspected)

Reason: Behavior disorders of childhood

Tablet

2 Dose Unspec Daily

Oral

Batch:

Started :

Stopped:

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Cases Count: 144

Case Number: 192350

Gender: M

Data Entry Date: 19/11/2003 Weight (kg): 0

Hospitalisation: Admitted to hospital Age:

DOB: 07/01/1994 Onset Date:

Outcome: Causality: Causality possible

Recovered

Onset occurred approximately 4 weeks after commencing Ritalin. The patient's lower Information:

limbs were extremely restrictive to movements, to the state where he 'could not walk'.

The patients upper limb movements were also reported somewhat restricted.

Reaction:

Preferred Term Severity **Report Description Treatment**

Caused or prolonged Ritalin had been ceased due to Hypertonia the event

inpatient hospitalisation

Myalgia Caused or prolonged

inpatient hospitalisation

Neuroleptic malignant Caused or prolonged

syndrome inpatient

hospitalisation

Medicine details:

Ritalin (Suspected) Reason:

> 20 Milligram Daily Oral

> > Details

Batch: Started: 21/10/2003 Stopped: 01/11/2003

Date Tested Result

Laboratory Investigations:

Type Range Other data

White blood cells 5-13 18/10/2003 13.3 **Platelets** 150-400 18/10/2003 401 C-Reactive Protein <5 18/10/2003 8.6

Sodium 133-143 18/10/2003 144

Mid-stream urine

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Cases Count: 144

Case Number: 192829

Gender: M

Data Entry Date: 04/12/2003 **Weight (kg)**: 0

Hospitalisation: Age: 13

Onset Date: 20/11/2003 **DOB**:

Outcome: 20/11/2003 Causality: Causality possible

Recovered

Information: Patient previously took Ritalin in 1999 and had loss of appetite.

Reaction:

Preferred Term Severity Report Description Treatment

Panic attack Panick attack, tremor, Ratilin La has been crying, heart rate discontinued

increased, confusional state, muscle twitching, dry mouth, headache, drained and

headache, drained and quiet, body aches, fatigue.

Confusional state

Crying

Dry mouth

Fatigue

Headache

Heart rate increased

Muscle twitching

Pain

Tremor

Medicine details:

Ritalin LA (Suspected) Reason: Behavior disorders of childhood

Capsule 40 Milligram Daily Oral

Batch: **Started**: 20/11/2003 **Stopped**: 21/11/2003

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Cases Count: 144

Gender: M

Case Number: 193009

Weight (kg): 55

Data Entry Date: 10/12/2003 **Hospitalisation:** Age:

Onset Date: 01/09/2003 **DOB**: 13/07/1989

Outcome: 02/10/2003 Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Visual field defect Required Visit to Blurring of perpheral vision.

Doctor

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 7.5 Milligram Daily Oral

Batch: Started: 05/04/2003 **Stopped:** 19/09/2003

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Cases Count: 144

Case Number: 193329

Gender: M

Data Entry Date: 18/12/2003 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information: Treatment with Ritalin had been ongoing for 9 years and the patient had not

experienced these symptoms before. The daily dose at the time of the event onset was 20mg. One black Ritalin tablet was also found in this batch which had been discarded. The patient ceased taking the tablets from this batch and received a new script. Batch B3002, expiry date Feb 2005. His conditions had not improved on the new Ritalin batch,

therefore treatment was discontinued.

Reaction:

Preferred Term Severity Report Description Treatment

Chest pain Chest pain, abdominal pain upper, diarrhoea, nausea.

Abdominal pain upper

Diarrhoea Nausea

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 1 Dose Unspec Daily Oral

Batch: Batch B 3002. Started: L TERM Stopped:

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Cases Count: 144

Case Number: 193410

Gender: M

Data Entry Date: 22/12/2003

Weight (kg): 0

Hospitalisation:

Age:

Onset Date:

DOB: 18/10/1994

Outcome:

Causality: Causality possible

Recovered

Information: Other drugs: Catapres, Ventolin and Flixotide. Dose start date: 02/2002. As a result of

the event the patient was given an extra Ritalin LA 10mg/tablet.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Drug ineffective

Drug ineffective, Appetite

increased NOS.

Increased appetite

Medicine details:

Ritalin LA (Suspected)

Reason: Behavior disorders of childhood

Capsule

30 Milligram

Daily

Oral

Batch: F3003

Started:

Stopped:

Contin

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Cases Count: 144

Case Number: 193412

Gender: F
Weight (kg): 0

Data Entry Date: 22/12/2003

Hospitalisation :

Age: 99U

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Lethargy

Very Lethargic, anaemia NOS, strong palpitations, fatigue, heart rate irregular, anxiety, nausea,

somnolence, pruritus and drug interaction NOS.

Anaemia

Anxiety

Fatigue

Heart rate irregular

Palpitations

Pruritus

Somnolence

Medicine details:

Ritalin LA (Interaction) Reason: Behavior disorders of childhood

Capsule 40 Milligram Daily Oral

Batch: Started: Stopped:

Tegretol (Interaction) Reason :

Tablet 200 Milligram Daily Oral

Batch: **Started**: 03/08/2003 **Stopped**: 04/08/2003

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Hospitalisation:

Outcome:

Public Case Detail

Cases Count: 144

Case Number: 193415

Gender: F

DOB:

Data Entry Date: 22/12/2003 **Weight (kg)**: 0

Age: 16Y

Onset Date: 10/08/2003

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Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Anxiety Anxiety attacks
Tachycardia Tachycardia Nos

Medicine details:

Ritalin LA (Suspected) Reason: Behavior disorders of childhood

Capsule 30 Milligram Daily Oral

Batch: **Started**: 10/08/2003 **Stopped**: 11/08/2003

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Cases Count: 144

Case Number : 195056

Gender: M

Data Entry Date: 01/03/2004 **Weight (kg)**: 0

Hospitalisation: Age: 6Y

Onset Date: 29/01/2004 **DOB**:

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Epistaxis Epistaxis - severe profuse nose bleeds within hours of

commencing Ritalin LA.
No nose bleeds were
experienced while he was

on Ritalin.

Medicine details:

Ritalin LA (Suspected) Reason: Behavior disorders of childhood

Capsule 30 Milligram Daily

Batch: **Started**: 29/01/2004 **Stopped**: 29/01/2004

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Hospitalisation:

Public Case Detail

Cases Count: 144

Case Number : 199877

Gender: M

Data Entry Date: 11/08/2004 **Weight (kg)**: 0

Age:

Onset Date: 15/05/2004

DOB: 31/10/1995

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Arrhythmia Required Specialist Patient experienced ECG performed. Changed back Consultation arrhythmia, tachycardia, to Ritalin.

Consultation arrhythmia, tachycardia, dizziness and drug

ineffective.

Dizziness Required Specialist

Consultation

Drug ineffective Required Specialist

Consultation

Tachycardia Required Specialist

Consultation

Medicine details:

Ritalin LA (Suspected) Reason: Behavior disorders of childhood

Capsule 30 Milligram Daily Oral

Batch: **Started**: 15/05/2004 **Stopped**: 0

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Cases Count: 144

Case Number: 201684

Gender: U

Data Entry Date: 13/10/2004 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date: 22/04/2004 **DOB**:

Outcome: 25/04/2004 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Ventricular fibrillation Ventric fibrillation, cardiac NB: Ritalin LA used. Ritalin

arrest. ceased.

Cardiac arrest

Medicine details:

Ritalin (Suspected) Reason :

60 Milligram Daily Oral

Batch: **Started**: 17/03/1995 L TERM **Stopped**: 22/04/2004 0

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Cases Count: 144

Case Number: 202677

Gender: F

Data Entry Date : 18/11/2004

Weight (kg): 0

Hospitalisation:

Age: 13

Onset Date: 15/10/2004

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Urticaria

Patient experienced an urticaria rash within 24

hours of commencing

Ritalin LA ceased. Antihistamines given.

Ritalin LA.

Medicine details:

Ritalin LA (Suspected)

Reason:

30 Milligram

Daily

Oral

Batch:

Capsule

Started: 15/10/2004

Stopped:

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Cases Count: 144

Case Number: 202887

Gender: U

Data Entry Date: 19/11/2004

Weight (kg): 22.6

Hospitalisation: Admitted to hospital

Age:

Onset Date:

DOB: 30/07/1997

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description**

OCD symptoms.

Treatment

Anxiety

Caused or prolonged inpatient

Patient developed significant anxiety and

hospitalisation

Caused or prolonged

Obsessive-compulsive disorder

inpatient

hospitalisation

Medicine details:

Dexamphetamine Sulphate (Suspected) Reason: Behavior disorders of childhood

> 10 Milligram Daily

Started: 15/04/2004 Batch:

Stopped: 15/06/2004

Ritalin (Suspected)

Reason: Behavior disorders of childhood

10 Milligram

Daily

Batch:

Started: 15/07/2004

Stopped: 15/09/2004

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Cases Count: 144

Gender: M

Case Number: 203217

Data Entry Date: 01/12/2004 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: 15/05/2004 **DOB**: 15/08/1988

Outcome : Causality : Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Retinal pigmentation Required Visit to Macula: abnormal Investigated, no treatment.

Doctor pigmentary granulation of

both maculae.

Medicine details:

Dexamphetamine Sulphate (Suspected) Reason: Unspecified neurosis

Batch: Started: L TERM Stopped:

Ritalin (Suspected) Reason: Unspecified neurosis

Oral

Batch: Started: L TERM Stopped:

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Cases Count: 144

Case Number: 203371

Gender: M

Data Entry Date: 08/12/2004

Weight (kg): 0

Hospitalisation:

Age: 8Y

Onset Date: 15/08/2004

DOB:

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Wheezing

Wheezing and urticaria.

Ceased Ritalin, treated with

steroids and antihistamines.

Urticaria

Medicine details:

Ritalin LA (Suspected)

Reason: Behavior disorders of childhood

Capsule

Batch:

20 Milligram

Daily

Oral

0

Started: 15/08/2004 Stopped: 30/08/2004

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Cases Count: 144

Case Number: 203398

Data Entry Date: 09/12/2004

Weight (kg): 75

Hospitalisation:

Age:

Gender: M

Onset Date: 27/09/2004

DOB: 13/03/1992

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Withdrawal syndrome

Preferred Term Severity

Report Description

Treatment Withdrawal state from Parents didn't seek medical taking Ritalin LA which advice regarding this reaction

lasted a week. Symtpoms

included visual hallucinations, distortions (objects varying in size), increased emotional lability, headaches,

nausea, vomiting, sweating and nervousness. At the time, he denied having taken any other

medications. After this period he has felt well. He reported having similar symptoms to a much lesser extent occasionally when overtired. He didn't have chest pain, abdominal pain, diarrhoea, sensations

of depersonalisation or derealisation.

distortions (objects varying

in size),

Visual impairment

Affect lability

Hallucination, visual

Headache

Hyperhidrosis

Nervousness

Vomiting

Medicine details:

Ritalin LA (Suspected)

Reason:

Daily

Oral

Batch:

Capsule

Started: 16/06/2003

Stopped: 27/09/2004

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60 Milligram



Cases Count: 144

Case Number : 204873

Gender: F

Data Entry Date: 03/02/2005 Weight (kg): 0
Hospitalisation: Age:

Onset Date: 15/01/2005 **DOB**: 04/08/1995

Outcome: 16/01/2005 Causality: Causality possible

Recovered

Information: Patient stabilised on Concedrta 36mg experienced insomnia, switched to Ritalin LA

40mg (had previously used Ritalin 30 before Conerta available). Stopped treatment for

school holidays. Restarted 15/01/05 and patient experienced reactions.

Reaction:

Preferred Term Severity Report Description Treatment

Choreoathetosis Choreoathetoid movements, severe

anorexia, tummy ache.

Abdominal pain upper

Decreased appetite

Medicine details:

Ritalin LA (Suspected) Reason: Behavior disorders of childhood

Capsule 40 Milligram Daily Oral

Batch: **Started**: 15/01/2005 **Stopped**: 0

Omeprazole (Other drug) Reason : Other diseases of esophagus

20 Milligram Daily

Batch: Started: L TERM Stopped:

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Hospitalisation:

Public Case Detail

Cases Count: 144

Case Number: 205291

Gender: M

Data Entry Date: 16/02/2005 **Weight (kg)**: 60

Age:

Onset Date: 04/02/2005

Outcome:

DOB: 05/02/1992

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Lethargy Required Visit to The patient experienced Doctor lethargy, headache, hot

cheeks and nausea half an hour after taking the second daily dose of

Ritalin.

Flushing Required Visit to

Doctor

Headache Required Visit to

Doctor

Nausea Required Visit to

Doctor

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

20 Milligram Daily Oral

Batch: Started: 29/01/2005 Stopped:

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Hospitalisation:

Public Case Detail

Cases Count: 144

Case Number: 206162

Gender: M

Oral

Data Entry Date: 17/03/2005 **Weight (kg)**: 0

Age:

Onset Date: 15/01/2005 DOB: 29/09/1995

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Vision blurred Patient experienced vision

disturbances such as blurred vision and flashes

of colour.

Daily

Visual impairment

Capsule

Medicine details:

Ritalin LA (Suspected) Reason : Behavior disorders of childhood

20 Milligram

Batch: Started: 15/09/2003 L TERM Stopped:

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Cases Count: 144

Case Number: 206905

Gender: M

Data Entry Date: 11/04/2005

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 24/02/2005

DOB: 14/11/1997

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Abnormal behaviour

Incapacity/disability

Uncontrollable, suddenly with dangerous behaviours, dose as a result of the events.

Zoloft given in an increased

hyperactive and drug

ineffective.

Drug ineffective

Incapacity/disability

Psychomotor hyperactivity

Incapacity/disability

Medicine details:

Ritalin LA (Suspected)

Reason: Behavior disorders of childhood

Capsule

20 Milligram

Daily

Oral

Batch: FA001

Started:

Stopped: 04/03/2005

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Cases Count: 144

He was decreased back to

Ritalin LA 20mg/day.

Gender: M

Case Number: 207373

Data Entry Date: 22/04/2005 Weight (kg): 0

Hospitalisation: Age: 11Y

Onset Date: 15/12/2004 DOB:

Causality: Causality possible Outcome:

Not yet recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Psychotic disorder The child's hallucinations and 'his psychosis got worse' after an increase in

Ritalin LA dose from 20mg/day to 40mg/day.

Hallucination

Therapy regimen changed

Medicine details:

Ritalin LA (Suspected) Reason:

Capsule 40 Milligram Oral Daily

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 209343

Gender: M

Data Entry Date: 30/06/2005

Weight (kg): 0

Hospitalisation:

Age: 11Y

Onset Date: 08/06/2005

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Amnesia

Caused or prolonged

inpatient hospitalisation

The child experienced loss of memory and was dazed during the day on 8 June 2005 after taking his usual

morning dose of Ritalin.

Feeling abnormal

Caused or prolonged

inpatient

hospitalisation

Medicine details:

Ritalin (Suspected)

Reason:

Tablet

Oral

Batch:

Started:

Stopped:

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Cases Count: 144

Case Number: 209472

Gender: M

Data Entry Date: 05/07/2005

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term
Weight increased

Report Description

Treatment

The child experienced excess weight gain whilst taking Ritalin LA. He had

been taking

Dexamphetamine and possibly Methylphenidate 10mg prior to being prescribed Ritalin LA.

Medicine details:

Ritalin LA (Suspected)

Reason:

Capsule

Oral

Batch:

Started:

Severity

Stopped:

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Cases Count: 144

Case Number : 209473

Gender: M

Data Entry Date: 05/07/2005

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information: Taking Methylphenidate 10mg tabs without weight gain.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Obesity

The child has become obese and cannot run without distress since taking Ritalin LA. He was

taking Ritalin LA. He was previously taking Methylphenidate 10mg tablets without weight gain.

Medicine details:

Ritalin LA (Suspected)

Reason:

Capsule

Oral

Batch:

Started:

Stopped:

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Cases Count: 144

Case Number: 209474

Gender: M

Data Entry Date: 05/07/2005 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date: DOB:

Outcome: Causality: Causality possible

Unknown

Information: Taking Methylphenidate 10mg tabs without weight gain.

Reaction:

Preferred Term Severity **Report Description Treatment**

Obesity

The child has become obese and cannot run without distress since taking Ritalin LA. He was taking Methylphenidate 10mg tablets without

weight gain prior to taking

Ritalin LA.

Medicine details:

Ritalin LA (Suspected) Reason:

Capsule Oral

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 210896

Gender: M

Data Entry Date: 18/08/2005 **Weight (kg)**: 0

Hospitalisation: Age: 12Y

Onset Date: 15/07/2005 **DOB**:

Outcome: Causality: Causality possible

Unknown

Information: Family history on father's side of depression.

Reaction:

Preferred Term Severity Report Description Treatment

Depression Patient complained that for the last month Ritalin was

making him depressed.

Medicine details:

Ritalin LA (Suspected) Reason :

Capsule 40 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 144

Ritalin ceased.

Case Number: 211209

Gender: F

Data Entry Date: 30/08/2005 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date: DOB:

Outcome: Causality: Causality possible

Recovered

Information: Newspaper report: Daily Telegraph 06/08/2005. Bitter little Pill?

Reaction:

Preferred Term Severity **Treatment Report Description** Growth retardation

The child experienced constant nausea, would not eat properly, was quiet and withdrawn and had trouble sleeping within weeks of commencing Ritalin. She was also noted to have 'stopped growing and went

from a happy, bubbly little girl to a gaunt, thin ghost of

herself'.

Decreased appetite

Insomnia

Nausea

Social avoidant behaviour

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 0.5 Dose Unspec Daily Oral

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 211693

Gender: M

Data Entry Date: 15/09/2005

Weight (kg): 35

Hospitalisation: Required a visit to the doctor

Age: 5Y

Onset Date: 24/07/2005

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Urticaria

The child developed

Treated with antihistamine,

urticaria and angioedema. Ritalin ceased.

Angioedema

Medicine details:

Ritalin (Suspected)

Reason:

20 Milligram

Daily

Oral

Batch:

Started: 10/07/2005

Stopped: 29/07/2005

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Cases Count: 144

Case Number: 211853

Gender: M

Data Entry Date: 22/09/2005 **Weight (kg)**: 0

Hospitalisation: Age: 17Y

Onset Date: 21/08/2005 **DOB**:

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Somnolence Incapacity/disability Patient experienced Ritalin was changed from 10mg

drowsiness on 21 Aug 2005, approximately 2 weeks after being switched

from Attenta.

x 3 to 10mg x2 dose.

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 30 Milligram Daily Oral

Batch: Started: 15/08/2005 Stopped:

Epilim (Other drug) Reason :

Batch: Started: Stopped:

Risperidone (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 212269

 Data Entry Date : 06/10/2005
 Weight (kg) : 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Anaemia Patient became very ill with anaemia as a result of

taking Ritalin. Patient also stopped eating and became dazed.

Confusional state
Decreased appetite

Medicine details:

Ritalin (Suspected) Reason :

Oral

Batch: Started: Stopped:

PUTRAN02 Page 100 of 146



Cases Count: 144

Case Number : 215535

Gender: M

Data Entry Date: 03/02/2006

Weight (kg): 0

Hospitalisation:

Age: 23Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Treatment

Unknown

Information:

Reaction:

Preferred Term
Tachycardia

Severity Report Description

30 Milligram

The patient experienced episodic tachycardia of 140

bpm.

Medicine details:

Ritalin (Suspected)

Reason:

Daily

Oral

Batch:

Started:

Stopped:

PUTRAN02 Page 101 of 146



Cases Count: 144

Case Number: 215892

Gender: M

Data Entry Date: 16/02/2006

Weight (kg): 0

Hospitalisation:

Age: 28Y

Onset Date: 31/01/2006

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Hallucination

The patient experienced side effects, irritability and three days of not good sleep, whilst on Ritalin. He also thought be had a

also thought he had a hallucination.

Irritability

Sleep disorder

Medicine details:

Ritalin (Suspected)

Reason: Behavior disorders of childhood

Tablet

30 Milligram

Daily

Oral

Batch:

Started: 31/01/2006

Stopped: 0

PUTRAN02 Page 102 of 146



Cases Count: 144

Case Number: 216810

Gender: M

Data Entry Date: 31/03/2006

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 15/04/1995

DOB: 13/01/1984

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Tic

Severity

Report Description

Treatment

Patient developed motor

tics

Medicine details:

Ritalin (Suspected)

 $\textbf{Reason:} \ \ \textbf{Behavior disorders of childhood}$

Batch:

Started: 07/03/1995

Stopped: 15/06/1995

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Hospitalisation:

Public Case Detail

Cases Count: 144

Case Number: 217768

Gender: M

Data Entry Date: 28/04/2006 **Weight (kg)**: 0

Age:

Onset Date: 13/04/2006

DOB: 06/02/1999

Outcome :

Causality: Causality possible

Unknown

Information:

Reaction:

Pruritus

Preferred Term Severity

Report Description

Treatment

Patient experienced

Ritalin ceased.

intense itchiness.

Medicine details:

Ritalin (Suspected)

Reason:

10 Milligram

Daily

Oral

Tablet Batch:

Started: 13/04/2006

Stopped: 13/04/2006

0 0

PUTRAN02 Page 104 of 146



Cases Count: 144

Gender: U

Case Number: 217907

Data Entry Date: 02/05/2006 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Suicidal ideation Child experienced various side-effects such as

suicidal thoughts whilst on

Ritalin.

Medicine details:

Ritalin (Suspected) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 105 of 146



Cases Count: 144

Case Number : 217971

Gender: M

Data Entry Date: 04/05/2006

Weight (kg): 0

Hospitalisation:

Age: 14Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity Report Description

Treatment

Vision blurred

Patient complained of

Requested to have an eye

experiencing blurred vision. examination.

Medicine details:

Ritalin (Suspected)

Reason:

50 Milligram

Daily

Oral

Batch:

Started:

Stopped :

0

PUTRAN02 Page 106 of 146



Cases Count: 144

Case Number: 218030

Gender: M

Data Entry Date: 05/05/2006 Weight (kg): 0

Hospitalisation: Age: 28Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: The patient had an intra-ocular lens implant at the age of 4 for an unspecified reasion

and the Implant had now been removed.

Reaction:

Preferred Term Severity Report Description Treatment

Intraocular pressure increased Patient experienced an

intraocular eye pressure of

28.

Medicine details:

Ritalin LA (Suspected) Reason : Anxiety neurosis

Capsule 20 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 144

Gender: F

Case Number: 218894

Data Entry Date: 03/06/2006 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: 14/05/2006 DOB: 16/07/1981

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Drug interaction Suspected drug interaction: Decreased dose of Seroquel After commencing Ritalin from 50mg to 25mg.

(increasing dose up to 10mg three times daily), patient noticed that the effect of Seroquel (50mg used once daily in the evening) was more

pronounced with a sudden "need" to sleep occuring within an hour of Seroquel dosing; and difficulty waking up in the morning followed by a "hangover" effect during the day.

Somnolence

Medicine details:

Ritalin (Interaction) Reason :

Tablet 30 Milligram Daily Oral

Seroquel (Interaction) Reason :

Tablet 50 Milligram Daily Oral

Batch: CX 371 **Started**: 15/03/2006 **Stopped**:

Efexor (Other drug) Reason : Otr ecz&der due otr&unsp cause

Capsule 300 Milligram Daily Oral

Batch: 70161A Started: Stopped:

PUTRAN02 Page 108 of 146



Cases Count: 144

Case Number: 219297 Gender: M

Data Entry Date: 20/06/2006 Weight (kg): 0

Hospitalisation: Age: 12Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Aggression

Patient developed aggression-started hitting kids, what he had never done befoe, the mother thought that the patient maybe was recognizing other kids taunts for the first time on Ritalin and thus response aggression.

Medicine details:

Ritalin (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 219446

Gender: M

Data Entry Date: 23/06/2006 **Weight (kg)**: 35

Hospitalisation : Age :

Onset Date: 02/11/2005 **DOB**: 31/08/1995

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Drug withdrawal syndrome Ritalin ceased 4 days ago

after weaning. Patient presented with 2 day history of drowsiness and

frontal headache.

Headache Somnolence

Medicine details:

Ritalin LA (Suspected) Reason :

 Capsule
 20 Milligram
 Daily
 Oral

 Batch :
 Started :
 L TERM
 Stopped : 30/10/2005

Flixotide (Other drug) Reason :

Inhalation 500 Microgram Inhalation

Batch: Started: Stopped:

Neulactil (Other drug) Reason :

Tablet 12.5 Milligram Daily Oral

Batch: Started: S TERM Stopped:

Ventolin (Other drug) Reason :

Inhalation 2 Dose Unspec Inhalation

Batch: Started: Stopped:

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Hospitalisation:

Public Case Detail

Cases Count: 144

Case Number: 220231

Gender: M

Data Entry Date: 20/07/2006 Weight (kg): 60

Age:

Onset Date: 19/05/2006 **DOB**: 19/08/1990

Outcome: 22/05/2006 Causality: Causality possible

Recovered

Information: 2 trials of this combination in this patient with identical problems both times full

resolution of problems once Roaccutane ceased.

Reaction:

Preferred Term Severity **Report Description Treatment**

Drug interaction Patient on long term Ceased Roaccutane

Methylphemdae for ADHD. Responding very well to this treatment. Intitated on Roaccutane for coexisting severe ache. Within 1-2 weeks symptoms of ADHD returned despite onging complaine with Ritalin. Problems noticed by patient, family and school teachers-Roaccutane was ceased. Symptoms resolved-within a few days

and his mental state

remains well.

Drug effect decreased

Medicine details:

Ritalin (Interaction) Reason: Behavior disorders of childhood

Capsule 40 Milligram Daily

Batch: Started: 18/09/2005 Stopped:

Roaccutane (Interaction) Reason: Other acne of sebaceous glands

Capsule 10 Milligram Daily

Stopped: 22/05/2006 Batch: Started: 20/03/2006

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Cases Count: 144

Case Number : 220887

Gender: F

Data Entry Date: 18/08/2006 **Weight (kg)**: 31

Hospitalisation: Age:

Onset Date: 14/07/2006 **DOB**: 02/02/1995

Outcome: Causality: Causality certain

Recovered

Information: Cert: Rechallenge .PH: Possible allergic rhinitis. Both parents have had allergic reaction

to antibiotics and antihistamines.

Reaction:

Preferred Term Severity Report Description Treatment

Eye oedema She developed puffiness of Ritalin withdrawn.

both eyes, sorness of the angle of jaw with some non-specific swelling in the area and pruritus of forearms 2 days after starting methylphenidate (Ritalin). Symptoms disappeared within 2 days of ceasing the Ritalin. Ritalin was restarted on 12/08/2006. The same symptoms recurred within

2 days.

Pain in jaw Pruritus

Swelling

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 5 Milligram 2 times Oral

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Hospitalisation:

Public Case Detail

Cases Count: 144

Case Number: 222921

Gender: M

Data Entry Date: 07/11/2006 **Weight (kg)**: 0

Age:

Onset Date: 01/07/2006

DOB: 07/02/1997

Outcome :

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Neoplasm malignant Dorsal coccygeal ependymona.

Medicine details:

Ritalin (Suspected) Reason :

Capsule 20 Milligram Daily Oral

Batch: **Started**: 01/05/2006 **Stopped**: 0

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Cases Count: 144

Case Number: 223299

Gender: M

Data Entry Date: 17/11/2006

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 05/10/2006

DOB: 06/10/1996

Outcome:

Causality: Causality possible

Unknown

Information: Product met all specs, only complaint against this batch.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Agitation Reacted badly

hyperexcitatory in nature,

agitation.

Product quality issue

Medicine details:

Ritalin LA (Suspected)

Reason: Behavior disorders of childhood

Capsule

30 Milligram

Daily

Oral

Batch: F4077

Started: 15/09/2006

Stopped: 0

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Cases Count: 144

Gender: F

Case Number: 224178

Data Entry Date: 19/12/2006 **Weight (kg)**: 0

Hospitalisation: Age: 60Y

Onset Date: 16/10/2006 **DOB**:

Outcome: 11/11/2006 Causality: Causality possible

Recovered

Information: SUSPECTED INTERACTION

Reaction:

Preferred Term Severity Report Description Treatment

Agitation Since starting Inner health, Ceased Inner Health.

patient is restless and excessively stimulated, wakes at 5.30am (prev 7am). Restless with incease distractability and decreased concentration.

Distractibility

Poor quality sleep

Restlessness

Medicine details:

Inner Health Plus (Interaction) Reason:

2 Dose Unspec Daily Oral

Batch: Started: 16/10/2006 **Stopped:** 10/11/2006

Ritalin (Interaction) Reason :

1 Dose Unspec Daily

Batch: Started: L TERM Stopped:

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Cases Count: 144

Case Number: 224469

Gender: M

Data Entry Date: 09/01/2007

Weight (kg): 0

Hospitalisation: Required a visit to the doctor

Age: 99U

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Electrocardiogram abnormal

Patient was clammy, anxious, complaining of having palpitation, feeling sick, nausea and vomiting,

electrocardiogram

abnormal.

Anxiety

Cold sweat

Malaise

Nausea

Palpitations

Vomiting

Medicine details:

Ritalin LA (Suspected)

Reason:

30 Milligram

Daily

Oral

Batch :

Capsule

Started :

Stopped:

PUTRAN02 Page 116 of 146



Cases Count: 144

Case Number : 226800

Gender: M

Data Entry Date: 21/03/2007

Weight (kg): 0

Hospitalisation :

Age:

Onset Date: 12/02/2007

DOB: 30/09/1975

Outcome: 12/02/2007

Causality: Causality possible

Recovered

Information:

History: Wisdom teeth removal and Dexamphetamine 5mg/2TID. Patient had previously been on Dexamphetamine and had stopped taking them approximately 4 to 5 days before commencing Ritalin LA. Patient had his wisdom teeth out, date not reported, and

has been on Panadeine Forte and tramadol but had ceased this 3 days prior to

commencing the Ritalin LA.

Reaction:

Preferred Term Severity

Report Description

several hours later.

Treatment

Lack of spontaneous speech

short period of time he was perspiring, felt disorientated, had a headache, fast heartbeat, his legs felt heavy, he felt like his "head was inside out" and he had trouble talking. The feelings abated but came back

Patient stated that within a

Disorientation

Headache

Heart rate increased

Hyperhidrosis

Sensation of heaviness

Medicine details:

Ritalin LA (Suspected) Reason: Behavior disorders of childhood

Capsule 40 Milligram Daily Oral

Batch: Started: 12/02/2007 Stopped:

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Cases Count: 144

Case Number : 226867

Gender: M

Data Entry Date: 22/03/2007

Weight (kg): 0

Hospitalisation:

Age: 99U

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Tic

Severity

Report Description

Treatment

Patient developed a tic.

Medicine details:

Ritalin LA (Suspected)

Reason:

1 Dose Unspec Weekly

Oral

Capsule

Batch:

Started:

Stopped:

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Cases Count: 144

Gender: M

Case Number: 227455

Data Entry Date: 10/04/2007 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: 22/02/2007 DOB: 05/02/1974

Outcome: Causality: Causality possible

Not yet recovered

Information: This is the second report of an individual falling from a balcony after taking zolpidem.

This victim is described as a long term user of sleeping medications and had been refused supply by some physicians. Newspaper article: The Manly Daily. 21 March 2007. Capozzi, Lisa. "Survivor to sue over pill claim". Also reported by another source.

Reaction:

Preferred Term Severity Report Description Treatment

Abnormal sleep-related event Caused or prolonged

inpatient hospitalisation friends (not known if alcohol consumed) went to his room, on the 12 th floor, to have a sleep. Had Stilnox with him, not sure if patient had taken it, patient fell onto restaurant roof. Patient had 2 fractured

Patient had had lunch with

vertebrae, fractured feet, ankle, shin, heel, nose both arms and damage to

tendons.

Fall Caused or prolonged

inpatient

hospitalisation

victim fell from a 12 storey

hotel balcony

Medicine details:

Ritalin (Suspected) Reason :

Tablet 5 Milligram Daily Oral

Batch: Started: L TERM Stopped:

Stilnox (Suspected) Reason: Specific disorders of sleep

Tablet 10 Milligram Daily Oral

Batch: **Started**: 15/08/2006 **Stopped**: 0

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Cases Count: 144

Case Number: 228378

Data Entry Date: 10/05/2007

Weight (kg): 0

Gender: M

Hospitalisation:

Age:

Onset Date: 18/03/2007

DOB: 02/06/1967

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Mass

Patient reported that Ritalin Dose decreased then stopped. would only last 45 minutes then the effect would "drop

off" and he would experience muscle pain, hot sweats, tightness in the chest andstomach area,

nausea and lumps in the arms below the elbow.

Abdominal discomfort

Chest discomfort

Drug effect decreased

Hyperhidrosis

Muscle twitching

Myalgia

Nausea

Oropharyngeal pain

Pain

Palpitations

Polydipsia

Polyuria

Pyrexia

Medicine details:

Reason: Cataplexy&narcolepsy brain dis

Tablet

60 Milligram

Daily

Oral

0

Ritalin (Suspected)

Batch:

Started: 18/03/2007

Stopped: 22/03/2007

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PUTRAN02



Cases Count: 144

Case Number: 229056

Gender: M

Data Entry Date: 30/05/2007

Weight (kg): 0

Hospitalisation:

Age: 8Y

Onset Date: 15/02/2007 DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Infection

Child experienced vomiting, weight loss, elevated markers showing

infection and white patches on the duodenal lining post-endoscopy.

Ritalin withheld for 1 week, referred to another paediatrician and a gastroenteroligist.

Duodenal scarring

Vomiting

Weight decreased

Medicine details:

Ritalin (Suspected)

Reason:

Daily

Oral

Batch :

Tablet

Started:

L TERM

Stopped:

Laboratory Investigations:

Type

Range

Date Tested Result

10 Milligram

Details

Endoscopy

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Cases Count: 144

Ceased medication.

Case Number: 229120

Gender: M

Data Entry Date: 30/05/2007 **Weight (kg)**: 0

Hospitalisation: Age: 11Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Suicidal ideation The patient tookStrattera for the treatment of ADHD

to complement Ritalin, under the influence of which he became suicidal

and depressed.

Depression

Drug ineffective

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Batch: Started: Stopped:

Strattera (Suspected) Reason: Behavior disorders of childhood

Capsule Oral

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 229750

Gender: M

Data Entry Date: 14/06/2007 Weight (kg): 80

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 15/11/2006 DOB: 28/03/1992

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Rash Patient experienced rash Ceased Ritalin.

over dorsal surface of forearms, consisting of discrete red maculopapular lesions which progress to breakdown and scab over, not itchy. None appear to be or become infected.

Rash maculo-papular

Medicine details :

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 10 Milligram Daily Oral

Batch: Started: Stopped: 08/02/2007

Ritalin LA (Suspected) Reason: Behavior disorders of childhood

Capsule 40 Milligram Daily Oral

Batch: Started: Stopped: 08/02/2007

Catapres (Other drug) Reason :

200 Microgram Daily

Batch: Started: L TERM Stopped:

PUTRAN02 Page 123 of 146



Cases Count: 144

Case Number: 230028

Gender: M

Data Entry Date: 21/06/2007 Weight (kg): 0

Hospitalisation: Age: 11Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hypothyroidism Child experienced hypothyroidism.

Medicine details:

Ritalin LA (Suspected) Reason : Behavior disorders of childhood

Capsule 30 Milligram Daily Oral

Batch: Started: Stopped:

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Hospitalisation:

Public Case Detail

Cases Count: 144

Case Number : 231283

Gender: M

Data Entry Date: 27/07/2007 **Weight (kg)**: 25

Age:

Onset Date: 30/06/2007 **DOB**: 05/12/1999

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Depression Depressive features, emotional lability, mood

disturbance

Affect lability
Mood altered

Medicine details:

Ritalin LA (Suspected) Reason :

Capsule 20 Milligram 1 time Oral

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 233136

Gender: F

Data Entry Date: 06/09/2007 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: DOB: 08/11/1989

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Pancreatitis Patient experienced

pancreatitis.

Medicine details:

Ritalin (Suspected) Reason :

Oral

Batch: Started: Stopped:

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Cases Count: 144

Gender: M

ritalin.

Case Number: 234040

Data Entry Date: 05/10/2007 **Weight (kg)**: 11.7

Hospitalisation: Age:

Onset Date : DOB : 07/08/2003

Outcome: 27/08/2007 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Stevens-Johnson syndrome Life threatening Child experienced more Stopped carbamazepine and

seizures, a florid erythematous rash on his face and back, small circular lesions on his arms and legs. He had bilateral conjunctivitis, his mouth and pharynx were red with small blisters on his lower lid mucous membrane and ulcers on bucal mucosa. He experienced diarrhoea, runny nose and coughing, stridor and facial oedema.

Conjunctivitis Life threatening

Cough Life threatening

Diarrhoea Life threatening

Face oedema Life threatening

Mouth ulceration Life threatening

Mouth ulceration Life threatening
Pharyngitis Life threatening

Rash erythematous Life threatening

Rhinitis Life threatening

Stridor Life threatening

Medicine details:

Carbamazepine (Suspected) Reason : Convulsions

80 Milligram Daily

Batch: Started: 07/08/2007 Stopped: 20/08/2007 0

Ritalin (Suspected) Reason: Behavior disorders of childhood

5 Milligram Daily

Batch: **Started**: 20/07/2007 **Stopped**: 18/08/2007

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Cases Count: 144

Case Number: 234956

Gender: U

Data Entry Date: 01/11/2007

Weight (kg): 0

Hospitalisation:

Age: 99U

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Psychiatric symptom

Severity

Report Description Treatment

The patient developed a psychiatric episode on an

unspecified date whilst on

Ritalin LA.

Medicine details:

Ritalin LA (Suspected)

Reason:

1 Dose Unspec Daily

Batch:

Started:

Stopped:

PUTRAN02 Page 128 of 146



Cases Count: 144

Case Number: 238430

Data Entry Date: 29/02/2008 **Weight (kg)**: 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Cardiomyopathy Patient experienced Ritalin ceased then cardiomyopathy whilst on reintroduced.

Ritalin.

Rita

Medicine details:

Ritalin (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 144

Case Number : 238798

Gender: F

Data Entry Date: 11/03/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: 14/01/2008 DOB: 24/12/1973

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Feeling abnormal Patient stated that two

weeks after commencing Ritalin she felt "spaced out", reqularly like she was "not present" in the

situation, depressed and

teary.

Depression

Tearfulness

Medicine details:

Ritalin (Suspected) Reason :

Tablet 30 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 239067

Gender: M

Data Entry Date: 18/03/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 19/02/2008

DOB: 04/02/1995

Outcome:

Causality: Causality possible

Not yet recovered

Information: Patient is also epileptic.

Reaction:

Preferred Term

Severity

Report Description

Treatment

Coma

Patient started Ritalin 10mg (BID) for almost four weeks for an unspecified indication. On 19 Feb 2008 (8-9 hours after his last dose) patient developed blurred vision, painful eyes, headaches, increased heart rate, swelling of face and lips, twitching, increase in body temperature and his face had turned yellow on that night. The patient started sweating and became confused and started hallucinating and felt that he had bugs on him and started shouting get these bugs off me (jerking). Patient's mother called the ambulance and the patient was taken to hospital where he was still confused and laughed for 10 minutes uncontrollably after which he eventually settled down. Doctors wanted to keep the patient in the hospital that night. but patient came home with his mother and slept well all night and had no recollection of things happened the next morning. Patient is still dazed and cannot remember much of what happened.

Confusional state

Dyskinesia

Eye pain

Formication

Heart rate increased

Hyperhidrosis

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Reaction:

Preferred Term Severity Report Description Treatment

Inappropriate affect

Lip swelling

Muscle twitching

Pallor

Swelling face

Vision blurred

Medicine details:

Epilim (Suspected) Reason :

1.2 Gram

Batch: Started: Stopped: 0

Ritalin (Suspected) Reason :

 Tablet
 20 Milligram
 Daily
 Oral

 Batch :
 Started : 15/01/2008
 Stopped : 19/02/2008

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Cases Count: 144

Case Number:239	3404	Gender: M

Data Entry Date: 31/03/2008 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

R	e	a	C	ti	O	n	•
	·	u	v	·	$\mathbf{}$		

Preferred Term Severity Report Description Treatment

Physical assault Patient had become

addicted to

methamphetamine

because of Ritalin use. The patient was jailed for 15 months for assault and an

act of indecency.

Asocial behaviour Drug dependence

Medicine details:

Ritalin (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 239999

Gender: M

Data Entry Date: 15/04/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date : DOB : 29/01/1988

Outcome: Causality: Causality possible

Unknown

Information: Use of Strattera which he stopped because of having suicidal thoughts.

Reaction:

Preferred Term Severity Report Description Treatment

Anger Patient was angrey and upset, self multation. head

feel fuzzy, depressed.

Depression

Feeling abnormal
Intentional self-injury

Medicine details:

Ritalin LA (Suspected) Reason: Behavior disorders of childhood

20 Milligram Daily

Batch: Started: 12/12/2007 Stopped:

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Cases Count: 144

Case Number: 242035

Gender: M

Data Entry Date: 18/06/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: 19/05/2008 DOB: 17/03/1958

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Anxiety Patient developed anxiety, confusion, and paranoia

when dose increased to

80mg.

Confusional state

Paranoia

Medicine details:

Ritalin (Suspected) Reason :

80 Milligram Daily Oral

Batch: Started: Stopped: 0

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Cases Count: 144

Case Number: 242258

Gender: M

Data Entry Date: 25/06/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Suicidal ideation Severity R

Report Description Treatment

Suicidal for 3 months, withdrawal reaction, hated the way it made him feel, was tired all the time, lost

weight.

Fatigue

Malaise

Weight decreased

Withdrawal syndrome

Medicine details:

Ritalin (Suspected)

Reason: Behavior disorders of childhood

Batch:

Started:

Stopped:

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Cases Count: 144

Case Number: 243412

Gender: M

Data Entry Date: 01/08/2008 **Weight (kg)**: 0

Hospitalisation: Age: 10Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

Information: Ritalin treatment was discontinued. The child was diagnosed correctly with Asperger's

syndrome, a form of autism, four years later.

Reaction:

Preferred TermSeverityReport DescriptionTreatmentTourette's disorderThe child developedRitalin ceased.

unusual eye movements and body spasms and was diagnosed with Tourette syndrome. The child

syndrome. The child started doing strange things and had full body tics and strange

movements with his eyes.

Abnormal behaviour

Aggression

Eye movement disorder

Muscle spasms

Tic

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Batch: Started: Stopped: 0

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Cases Count: 144

Case Number: 243686

Gender: M

Data Entry Date: 11/08/2008

Weight (kg): 0

Hospitalisation:

Age: 7Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Depression

Life threatening

Patient became depressed

and tried to commit suicide.

Suicide attempt

Life threatening

Medicine details:

Ritalin (Suspected)

Reason:

Batch:

Started:

S TERM

Stopped:

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Cases Count: 144

Case Number: 243693

Data Entry Date: 11/08/2008 **Weight (kg)**: 0

Hospitalisation: Age: 12Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Suicidal ideation Patient became obsessed with dead bodies and

hanging himself.

Obsessive thoughts

Medicine details:

Ritalin (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 144

Gender: M

Case Number: 244192

Data Entry Date: 27/08/2008 **Weight (kg)**: 0

Hospitalisation: Required a specialist consultation Age:

Onset Date: 27/07/2008 DOB: 29/12/1993

Outcome : Causality : Causality possible

Recovered

Information: Experiencing seizures about two years ago while on methylphenidate. Diagnosed as

primary generalised epilepsy, manifesting as photosensitive seizures. Treated with

Epilim.

Reaction:

Preferred Term Severity Report Description Treatment

Convulsion Two days after starting Ceased Atomoxetine. atomoxetine, the patient Methylphenidate recommenced.

atomoxetine, the patient experienced a convulsion. Pt was initially on Ritalin (methylphenidate) but was switched to Strattera

Switched to Stratter

(Atomoxetine

hydrochloride) because Ritalin had an effect on the pts growth (as stated by the treating physician). the patient had a past history of seizures and was already on on sodium valproate 400mg bd

Medicine details:

Ritalin (Suspected) Reason :

Batch: Started: Stopped:

Strattera (Suspected) Reason :

Capsule

Batch: **Started**: 25/07/2008 **Stopped**: 27/07/2008 0

Epilim (Other drug) Reason :

2 times Oral

Batch: Started: Stopped: 0

Laboratory Investigations:

Type Range Date Tested Result Details

Other data 350-700 (no 27/07/2008 467 epilim level 467

units)

Electroencephalograph 27/07/2008 abn abnormal bifrontal spike wave and photo

peroxyl response

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Cases Count: 144

Case Number: 244987

Gender: M

Data Entry Date: 30/09/2008 **Weight (kg)**: 0

Hospitalisation: Age: 8Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Psychotic disorder Psychotic disorder Ceased ritalin

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 245434

Gender: M

Data Entry Date: 14/10/2008 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: The reporter was later told that her son was misdiagnosed.

Reaction:

Preferred Term Severity Report Description Treatment

Suicide attempt Patient experienced

stopped growth and height and tried to commit suicide.

Growth retardation

Medicine details:

Ritalin (Suspected) Reason :

Batch : Started : Stopped :

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Cases Count: 144

Case Number : 245436

Gender: M

Data Entry Date: 14/10/2008 **Weight (kg)**: 0

Hospitalisation: Age: 17Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information: Possibility if the original diagnosis was wrong.

Reaction:

Sexual abuse

Preferred Term Severity Report Description Treatment

Teenage patient with history of abnormal behaviour was on Ritalin for ADHD from unknown date for two years.
Previous to receiving Ritalin, the patient was prescribed the stimulant

Ritalin, the patient was prescribed the stimulant dexamphetamine from the age of 7 years untill 12 years. The patient was jailed for three years for attempted sexual assault. He had been drinking, and used the drug "ice" for the first time before he attempted the sexual assault. It was reported

assault. It was reported that there was a possibility if the original diagnosis was wrong, then it was likely that his intellectual and psychological development

had been severely

affected.

Alcohol abuse Drug abuse

Medicine details:

Dexamphetamine Sulphate (Suspected) Reason :

Batch: Started: Stopped:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 1 Dose Unspec Daily Oral

Batch: Started: Stopped:

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Cases Count: 144

Case Number: 252639

Data Entry Date: 23/06/2009 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date: 29/05/2009 DOB: 02/05/2001

Outcome: 16/07/2009 Causality: Causality probable

Recovered

Information: Positive dechallenge

Reaction:

Preferred Term Severity Report Description Treatment

Hallucination

Patient experienced
hallucinations of spiders
crawling on skin at 4-5 pm

of each day since 29 May

2009.

Medicine details:

Ritalin (Suspected) Reason :

Oral

Gender: M

Batch: Started: 20/03/2009 Stopped:

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Cases Count: 144

Case Number: 253830

Gender: M

Data Entry Date: 15/07/2009

Weight (kg): 0

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity **Report Description** **Treatment**

Dystonia

Patient developed dystonia

Suggested deep brain

and blepharospasms.

stimulation.

Blepharospasm

Medicine details:

Ritalin (Suspected)

Reason:

1 Dose Unspec Daily

Oral

Batch:

Started:

Stopped:

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Cases Count: 144

Gender: F

Age:

Ritalin ceased.

Case Number: 255609

Data Entry Date: 19/08/2009 Weight (kg): 39.5

Hospitalisation:

Onset Date: 01/07/2009 DOB: 19/10/1998

Outcome: 01/07/2009 Causality: Causality certain

Recovered

Information: Cert: rechall

Reaction:

Preferred Term Severity Report Description Treatment

Lip swelling Patient was given 10mg of

Ritalin and developed swollen sore lips within 2 hours. Subsequent cracking of lips with resolution over 48 hours. Subsequently given 5mg and 2.5mg with same reaction. None since. At same time had been on Concerta 18 and Concerta given with no adverse response. She is now

taking Concerta 27 with no

S-Es.

Chapped lips

Medicine details:

Ritalin (Suspected) Reason: Behavior disorders of childhood

Tablet 10 Milligram 1 time Oral

Concerta (Other drug) Reason :

Batch: Started: Stopped:

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

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