

Public Case Detail

Case Number : 24167

Data Entry Date : 10/12/1980

Hospitalisation :

Onset Date :

Outcome :

Recovered

Gender : M

Weight (kg) :

Age : 59Y

DOB :

Causality : Causality possible

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| Prothrombin level decreased | | | Drugs withdrawn.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 malign lymphoid tissue

Tablet 20 Milligram Daily Oral

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

WARFARIN SODIUM (Interaction)

Reason : Otr prim malign lymphoid tissue

Tablet 7.5 Milligram Alternate days Oral

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

WARFARIN SODIUM (Interaction)

Reason : Otr prim malign lymphoid tissue

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% |

Public Case Detail

Case Number : 24796

Data Entry Date : 13/03/1981

Gender : F

Hospitalisation :

Weight (kg) : 53

Onset Date : 22/02/1981

Age : 70Y

Outcome :

DOB :

Recovered

Causality : Causality possible

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 | 2 Dose Unspec | Daily | Oral |
| Batch : | Started : 20/02/1981 | Stopped : | CONTIN |
| CODEINE PHOSPHATE (Other drug) | | Reason : Diarrhea | |
| Tablet | 30 Milligram | Daily | Oral |
| Batch : | Started : 21/02/1981 | Stopped : 21/02/1981 | |
| MAXOLON (Other drug) | | Reason : Nausea and vomiting | |
| Tablet | 10 Milligram | Daily | Oral |
| Batch : | Started : 20/02/1981 | Stopped : 22/02/1981 | |
| NITRAZEPAM (Other drug) | | Reason : Specific disorders of sleep | |
| Tablet | 5 Milligram | Daily | Oral |
| 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. |

Public Case Detail

Case Number : 25836

Data Entry Date : 01/09/1981

Hospitalisation :

Onset Date : 22/07/1981

Outcome :
Recovered

Gender : M

Weight (kg) :

Age : 05Y

DOB :

Causality : Causality possible

Information:

| Reaction : | | | |
|-------------------------|-----------------|---------------------------|---------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Dyskinesia | | | |
| Dystonia | | | |
| Extrapyramidal disorder | | | Ritalin withdrawal. |
| Oculogyric crisis | | | |

| Medicine details : | | | |
|--------------------------------|-----------------------------|--|------|
| RITALIN (Suspected) | | Reason : Behavior disorders of childhod | |
| 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 : | |

Public Case Detail

Case Number : 74013

Data Entry Date : 29/10/1991

Hospitalisation :

Onset Date : 31/08/1991

Outcome :
Recovered

Gender : F

Weight (kg) : 61

Age : 81Y

DOB :

Causality : Causality possible

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 : | Started : | Stopped : 31/08/1991 | |
| ASPIRIN (Other drug) | | Reason : | |
| | | 150 Milligram Daily | |
| Batch : | Started : | Stopped : | CONTIN |
| GLYCERYL TRINITRATE (Other drug) | | Reason : | |
| Cream | | 10 Milligram Daily | Topical |
| Batch : | Started : | Stopped : | CONTIN |

Public Case Detail

Case Number : 74228

Data Entry Date : 20/11/1991

Gender : M

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

Public Case Detail

Case Number : 92719

Data Entry Date : 03/05/1994

Hospitalisation :

Onset Date : 30/09/1992

Outcome :

Not yet recovered

Gender : M

Weight (kg) : 21

Age : 8Y

DOB :

Causality : Causality possible

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

Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|------------|-------|-------------|--------|--|
| Other data | | | | Vision (currently 3/60 l eye and 1/60 r eye) & ngus of optic atrophy. |

Public Case Detail

Case Number : 102717

Data Entry Date : 09/08/1995

Gender : F

Hospitalisation :

Weight (kg) : 26

Onset Date : 02/05/1995

Age : 9Y

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 right | Stopped night dose of ritalin. |

Medicine details :

| | | |
|----------------------------|-----------------------------|------------------|
| RITALIN (Suspected) | Reason : | |
| Tablet | 2.5 Dose Unspec Daily | Oral |
| Batch : | Started : 01/10/1994 | Stopped : |

Public Case Detail

Case Number : 104753

Data Entry Date : 21/11/1995

Gender : M

Hospitalisation :

Weight (kg) : 34

Onset Date :

Age : 99u

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

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 |
|------------------|----------|--------------------|-----------|
| Anorexia | | | |
| 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 : |

Public Case Detail

Case Number : 106364

Data Entry Date : 09/02/1996

Hospitalisation :

Onset Date : 01/02/1996

Outcome :
Recovered

Gender : M

Weight (kg) : 22

Age : 5Y

DOB :

Causality : Causality probable

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 |

Public Case Detail

Case Number : 114965

Data Entry Date : 04/02/1997

Hospitalisation :

Onset Date : 31/12/1996

Outcome :

Not yet recovered

Gender : M

Weight (kg) : 24

Age : 5Y

DOB :

Causality : Causality certain

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

Public Case Detail

Case Number : 116359

Gender : F

Data Entry Date : 26/03/1997

Weight (kg) :

Hospitalisation :

Age : 72Y

Onset Date : 28/02/1997

DOB :

Outcome :

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 | |
| Batch : | 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 | |

Public Case Detail

Case Number : 116969

Data Entry Date : 21/04/1997

Gender : M

Hospitalisation :

Weight (kg) : 45

Onset Date : 30/03/1997

Age : 13Y

Outcome :

DOB :

Unknown

Causality : Causality possible

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, catapres 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 : | |

Public Case Detail

Case Number : 119128

Data Entry Date : 16/07/1997

Gender : M

Hospitalisation :

Weight (kg) : 90

Onset Date : 04/07/1997

Age : 14Y

Outcome :

DOB :

Recovered

Causality : Causality possible

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 : | |

Public Case Detail

Case Number : 120273

Data Entry Date : 25/08/1997

Gender : M

Hospitalisation :

Weight (kg) : 45

Onset Date : 31/01/1997

Age : 11Y

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 :

Public Case Detail

Case Number : 120281

Data Entry Date : 26/08/1997

Gender : M

Hospitalisation :

Weight (kg) : 21

Onset Date : 24/07/1997

Age : 6Y

Outcome :

DOB :

Recovered

Causality : Causality certain

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 | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-------------|
| Rash | | | Polaramine. |

Medicine details :

| | |
|----------------------------|---|
| RITALIN (Suspected) | Reason : |
| | 5 Milligram Daily |
| Batch : | Started : 18/07/1997 Stopped : 20/07/1997 |

Public Case Detail

Case Number : 121575

Gender : U

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 reinstated 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 |
| Batch : | Started : | Stopped : | |
| PROTAPHANE (Interaction) | | Reason : Diabetes mellitus | |
| Injection | 2 Unit | Daily | Subcutaneous |
| Batch : | Started : | Stopped : | |
| RITALIN (Interaction) | | Reason : | |
| Oral application | 35 Milligram | Daily | Oral |
| Batch : | Started : 01/04/1996 | Stopped : | CONTIN |
| CLONIDINE HYDROCHLORIDE (Other drug) | | Reason : | |
| | 150 Microgram | Daily | |
| Batch : | Started : | Stopped : | |

Public Case Detail

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 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 | | | |

Medicine details :

| | |
|---------------------------------|---|
| 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 : |

Public Case Detail

Case Number : 123253

Gender : F

Data Entry Date : 10/12/1997

Weight (kg) :

Hospitalisation :

Age : 67Y

Onset Date : 08/10/1997

DOB :

Outcome :

Causality : Causality possible

Death, maybe drug

Information: Patient died 12/10/97.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|-----------------------|---|
| Hallucination | | Visual hallucinations | |
| Confusional state | | | Ceased ritalin and changed to morphine mix. |

Medicine details :

| | |
|--|---|
| CIPROFLOXACIN (Suspected) | Reason : Unspecified septicemia |
| Tablet | 1.5 Gram Daily Oral |
| Batch : | Started : 29/09/1997 Stopped : 08/10/1997 |
| COLOXYL WITH SENNA (Suspected) | Reason : Constipation |
| Tablet | 4 Dose Unspec Daily Oral |
| Batch : | Started : 29/09/1997 Stopped : 08/10/1997 |
| DOTHIPIIN HYDROCHLORIDE (Suspected) | Reason : |
| | 75 Milligram 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 |
| Tablet | 40 Milligram Daily Oral |
| Batch : | Started : 29/09/1997 Stopped : 08/10/1997 |
| PANADOL (Suspected) | Reason : Pain |
| Oral application | 4 Gram Daily Oral |
| Batch : | Started : 30/09/1997 Stopped : 08/10/1997 |
| RITALIN (Suspected) | Reason : |
| Tablet | 10 Milligram Daily Oral |
| Batch : | Started : 07/10/1997 Stopped : 08/10/1997 |
| SLOW-K (Suspected) | Reason : |
| | 2 Dose Unspec Daily |
| Batch : | Started : 29/09/1997 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 |

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

Public Case Detail

Case Number : 124338

Data Entry Date : 22/01/1998

Hospitalisation :

Onset Date :

Outcome :

Recovered

Gender : M

Weight (kg) : 29

Age : 9Y

DOB :

Causality : Causality probable

Information:

| Reaction : | | | |
|-----------------------|-----------------|--|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Hallucination | | Tactile hallucinations, visual hallucinations. | Ceased ritalin. |

| Medicine details : | | | |
|----------------------------|-----------------------------|--|------|
| RITALIN (Suspected) | | Reason : Behavior disorders of childhod | |
| Tablet | 30 Milligram | Daily | Oral |
| Batch : | Started : 24/07/1997 | Stopped : 05/12/1997 | |

Public Case Detail

Case Number : 125581

Data Entry Date : 06/03/1998

Gender : M

Hospitalisation :

Weight (kg) :

Onset Date : 20/02/1998

Age : 15Y

Outcome :

DOB :

Recovered

Causality : Causality possible

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 : | |

Public Case Detail

Case Number : 131913

Data Entry Date : 09/10/1998

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 30

Onset Date :

Age : 6Y

Outcome :

DOB :

Unknown

Causality : Causality certain

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 : | |

Public Case Detail

Case Number : 132576

Data Entry Date : 30/10/1998

Hospitalisation :

Onset Date : 22/10/1998

Outcome :
Unknown

Gender : F

Weight (kg) : 20

Age : 3Y

DOB :

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|---|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Dyskinesia | | Orobuccal dyskinesia/lip-smack.tongue protrusions | Ceased ritalin. |

| Medicine details : | | | |
|----------------------------|---|-----------------------------|------|
| RITALIN (Suspected) | Reason : Behavior disorders of childhood | | |
| Tablet | 15 Milligram | Daily | Oral |
| Batch : | Started : 22/10/1998 | Stopped : 22/10/1998 | |

Public Case Detail

Case Number : 135266

Data Entry Date : 20/01/1999

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : M

Weight (kg) :

Age : AC

DOB :

Causality : Causality possible

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 : |

Public Case Detail

Case Number : 136672

Data Entry Date : 26/02/1999

Hospitalisation :

Onset Date :

Outcome :

Recovered

Gender : F

Weight (kg) :

Age : A2

DOB :

Causality : Causality possible

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 :

Started :

Stopped :

Public Case Detail

Case Number : 137983

Data Entry Date : 30/03/1999

Hospitalisation :

Onset Date : 31/07/1995

Outcome :
Recovered

Gender : M

Weight (kg) :

Age : 11Y

DOB :

Causality : Causality possible

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 disorder in structured form | Ceased all medication |

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 : |

Public Case Detail

Case Number : 140184

Data Entry Date : 02/06/1999

Hospitalisation :

Onset Date : 31/05/1999

Outcome :
Unknown

Gender : F

Weight (kg) :

Age : 11Y

DOB : 28/02/1988

Causality : Causality possible

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 | Treatment |
|------------------|----------|-----------------------------|-----------|
| Drug ineffective | | Loss of behavioural control | |

Medicine details :

| | | | |
|----------------------------|------------------|---|------|
| RITALIN (Suspected) | | Reason : Behavior disorders of childhood | |
| Tablet | 0 | Daily | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Case Number : 140212

Data Entry Date : 02/06/1999

Gender : M

Hospitalisation :

Weight (kg) : 59

Onset Date : 08/05/1999

Age : 13Y

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 childhod

Tablet

0.5 Dose Unspec Daily

Oral

Batch :

Started : 08/05/1999

Stopped : 08/05/1999

Public Case Detail

Case Number : 140311

Data Entry Date : 07/06/1999

Hospitalisation :

Onset Date : 17/05/1999

Outcome :
Recovered

Gender : M

Weight (kg) :

Age : 10Y

DOB : 20/04/1989

Causality : Causality possible

Information: Patient has been on ritalin for approximately 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 Milligram Daily Oral |
| Batch : | Started : 01/06/1998 Stopped : |
| CATAPRES (Other drug) | Reason : |
| | 0 |
| Batch : | Started : Stopped : |
| CLONIDINE HYDROCHLORIDE (Other drug) | Reason : |
| | 0 |
| Batch : | Started : Stopped : |

Public Case Detail

Case Number : 140625

Data Entry Date : 16/06/1999

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : F

Weight (kg) :

Age : 10Y

DOB :

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|--|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Alopecia | | Lge bald patch on crown & frontal section of head. | |

| Medicine details : | | | |
|----------------------------|------------------|------------------|------|
| RITALIN (Suspected) | | Reason : | |
| Tablet | 55 Milligram | Daily | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Case Number : 140767

Data Entry Date : 21/06/1999

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : U

Weight (kg) :

Age :

DOB :

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|---------------------------|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Tremor | | Shaking uncontrollably | |
| Aggression | | | |
| Neurosis | | | |

| Medicine details : | | | |
|----------------------------|------------------|------------------|--|
| RITALIN (Suspected) | Reason : | | |
| Tablet | 0 | Oral | |
| Batch : | Started : | Stopped : | |

Public Case Detail

Case Number : 140877

Data Entry Date : 24/06/1999

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : U

Weight (kg) :

Age :

DOB :

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|---------------------------|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Tooth discolouration | | | |

| Medicine details : | | | |
|----------------------------|------------------|------------------|------|
| RITALIN (Suspected) | Reason : | | |
| Tablet | 0 | Daily | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Case Number : 140972

Data Entry Date : 29/06/1999

Gender : U

Hospitalisation :

Weight (kg) :

Onset Date :

Age :

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|---------------------------|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Weight decreased | | | |

| Medicine details : | | | |
|----------------------------|------------------|---|------|
| RITALIN (Suspected) | | Reason : Behavior disorders of childhood | |
| Tablet | 0 | Daily | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Case Number : 140974

Data Entry Date : 29/06/1999

Gender : M

Hospitalisation :

Weight (kg) :

Onset Date : 31/05/1999

Age : 04Y

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 | Severity | Report Description | Treatment |
|----------------|----------|--|-----------------------|
| Vomiting | | Gagging/dry retching and wanting to vomit. | |
| Abdominal pain | | Patient experienced a sore stomach. | |
| Nervousness | | Patient was irritable (easily cried). | Ritalin discontinued. |
| Anorexia | | | |
| Headache | | | |

Medicine details :

| | | | |
|----------------------------|-----------------------------|------------------|------------|
| RITALIN (Suspected) | | Reason : | |
| Tablet | 0 | Daily | Oral |
| Batch : | Started : 10/05/1999 | Stopped : | 15/05/1999 |

Public Case Detail

Case Number : 142567

Data Entry Date : 11/08/1999

Hospitalisation :

Onset Date : 31/12/1999

Outcome :
Unknown

Gender : M

Weight (kg) :

Age : 16Y

DOB : 12/11/1982

Causality : Causality possible

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 : | |

Public Case Detail

Case Number : 142958

Data Entry Date : 24/08/1999

Hospitalisation :

Onset Date : 31/05/1999

Outcome :
Recovered

Gender : F

Weight (kg) : 40

Age : 10Y

DOB :

Causality : Causality possible

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 : |

Public Case Detail

Case Number : 143438

Gender : M

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 : | |

Public Case Detail

Case Number : 143680

Data Entry Date : 13/09/1999

Hospitalisation :

Onset Date : 20/08/1999

Outcome :
Recovered

Gender : M

Weight (kg) :

Age : 11Y

DOB :

Causality : Causality possible

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 ritalin was not working | The reaction stopped with use of catapres and discontinuation of ritalin. |

Medicine details :

| | | | |
|----------------------------|-----------------------------|-----------------------------|------|
| RITALIN (Suspected) | | Reason : | |
| Tablet | 30 Milligram | Daily | Oral |
| Batch : LOTB056700 | Started : 30/03/1995 | Stopped : 25/08/1999 | |

Public Case Detail

Case Number : 143687

Data Entry Date : 13/09/1999

Gender : F

Hospitalisation :

Weight (kg) :

Onset Date : 31/08/1999

Age : 8Y

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 |

Public Case Detail

Case Number : 143689

Data Entry Date : 13/09/1999

Hospitalisation :

Onset Date : 31/12/1996

Outcome :
Unknown

Gender : M

Weight (kg) :

Age :

DOB :

Causality : Causality possible

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 |

Public Case Detail

Case Number : 144534

Data Entry Date : 11/10/1999

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : M

Weight (kg) :

Age : 12Y

DOB : 11/01/1987

Causality : Causality possible

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 : | Started : | Stopped : | |
| RITALIN (Suspected) | | Reason : Behavior disorders of childhood | |
| Tablet | 50 Milligram | Daily | Oral |
| Batch : | Started : 01/01/1996 | Stopped : | CONTIN |

Public Case Detail

Case Number : 145127

Data Entry Date : 27/10/1999

Hospitalisation :

Onset Date : 20/10/1999

Outcome :
Unknown

Gender : M

Weight (kg) :

Age : 15Y

DOB :

Causality : Causality possible

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 : | |

Public Case Detail

Case Number : 145130

Data Entry Date : 27/10/1999

Gender : F

Hospitalisation :

Weight (kg) :

Onset Date : 31/12/1999

Age : 50Y

DOB : 09/08/1949

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 |
|----------------|----------|--|-----------|
| Headache | | Headaches | |
| 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 Daily Oral |
| Batch : | Started : 01/01/1999 Stopped : CONTIN |
| 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 : |

Public Case Detail

Case Number : 147205

Data Entry Date : 20/12/1999

Hospitalisation :

Onset Date : 17/11/1999

Outcome :

Not yet recovered

Gender : M

Weight (kg) :

Age : 5Y

DOB : 24/10/1994

Causality : Causality possible

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 |
|----------------|----------|--|-------------|
| Rash | | Scaley scaby thing on head. pt scratching the area | Antibiotics |
| Infection | | | |

Medicine details :

RITALIN (Suspected)

Reason : Behavior disorders of childhod

Tablet

5 Milligram

Daily

Oral

Batch :

Started : 01/09/1999

Stopped :

CONTIN

Public Case Detail

Case Number : 147288

Data Entry Date : 20/12/1999

Hospitalisation :

Onset Date : 23/11/1999

Outcome :
Unknown

Gender : F

Weight (kg) :

Age : 37Y

DOB : 27/07/1962

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|---------------------------|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Pancreatitis | | | |

| Medicine details : | | | |
|------------------------------|-----------------------------|------------------|------|
| RITALIN (Suspected) | | Reason : | |
| Tablet | 10 Milligram | Daily | Oral |
| Batch : | Started : 09/11/1999 | Stopped : | |
| AROPAX (Other drug) | | Reason : | |
| | 0 | | |
| Batch : | Started : | Stopped : | |
| ENTOCORT (Other drug) | | Reason : | |
| | 0 | | |
| Batch : | Started : | Stopped : | |
| KAPANOL (Other drug) | | Reason : | |
| | 0 | | |
| Batch : | Started : | Stopped : | |

| Laboratory Investigations : | | | | |
|------------------------------------|--------------|--------------------|---------------|-----------------|
| Type | Range | Date Tested | Result | Details |
| Amylase | | | | Raised amylase. |

Public Case Detail

Case Number : 148166

Data Entry Date : 17/01/2000

Hospitalisation :

Onset Date : 05/01/2000

Outcome :
Unknown

Gender : M

Weight (kg) :

Age : 9Y

DOB :

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|---------------------------------|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Apathy | | Withdrawn and unusual behaviour | |
| Withdrawal syndrome | | | |

| Medicine details : | | | |
|--|------------------|---|------|
| 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 : | |

Public Case Detail

Case Number : 150682

Data Entry Date : 22/03/2000

Gender : U

Hospitalisation :

Weight (kg) :

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 : | |
| Tablet | 10 Milligram | Daily | Oral |
| Batch : | Started : 01/01/1999 | Stopped : | CONTIN |

Public Case Detail

Case Number : 151227

Data Entry Date : 03/04/2000

Gender : M

Hospitalisation :

Weight (kg) :

Onset Date :

Age : 6Y

Outcome :

DOB : 25/08/1993

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 |

Public Case Detail

Case Number : 152295

Data Entry Date : 01/05/2000

Hospitalisation :

Onset Date : 31/12/1997

Outcome :
Unknown

Gender : M

Weight (kg) :

Age : 15Y

DOB : 25/03/1985

Causality : Causality certain

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 childhod | | |
| Tablet | 30 Milligram | Daily | Oral |
| Batch : | Started : 01/12/1997 | Stopped : 17/04/2000 | |

Public Case Detail

Case Number : 152528

Data Entry Date : 10/05/2000

Gender : F

Hospitalisation :

Weight (kg) :

Onset Date :

Age :

Outcome :

DOB :

Unknown

Causality : Causality possible

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 |
|----------------|----------|--------------------|----------------|
| Abdominal pain | | Stomach pains | Ceased ritalin |

Medicine details :

| | | | |
|----------------------------|-----------------------------|---|------|
| RITALIN (Suspected) | | Reason : Behavior disorders of childhood | |
| Tablet | 0 | | Oral |
| Batch : | Started : 01/02/2000 | Stopped : | |

Public Case Detail

Case Number : 153009

Data Entry Date : 24/05/2000

Gender : M

Hospitalisation :

Weight (kg) :

Onset Date :

Age : 4Y

Outcome :

DOB :

Unknown

Causality : Causality possible

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 |

Public Case Detail

Case Number : 153411

Data Entry Date : 05/06/2000

Gender : M

Hospitalisation :

Weight (kg) :

Onset Date : 23/05/2000

Age : 07Y

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 |

Public Case Detail

Case Number : 155468

Data Entry Date : 24/07/2000

Hospitalisation :

Onset Date : 31/12/2000

Outcome :
Unknown

Gender : F

Weight (kg) :

Age : 12Y

DOB :

Causality : Causality possible

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 |
|----------------|----------|--------------------|-----------|
| Anorexia | | | |

Medicine details :

| | | | |
|----------------------------|---|------------------|--------|
| RITALIN (Suspected) | Reason : Behavior disorders of childhood | | |
| Tablet | 50 Milligram | Daily | Oral |
| Batch : | Started : 01/01/1999 | Stopped : | CONTIN |

Public Case Detail

Case Number : 155469

Data Entry Date : 24/07/2000

Hospitalisation :

Onset Date : 31/12/2000

Outcome :
Unknown

Gender : M

Weight (kg) :

Age : 9Y

DOB :

Causality : Causality possible

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 |
|----------------|----------|--------------------|-----------|
| Anorexia | | | |

Medicine details :

| | | | |
|----------------------------|---|------------------|--------|
| RITALIN (Suspected) | Reason : Behavior disorders of childhood | | |
| Tablet | 35 Milligram | Daily | Oral |
| Batch : | Started : 01/01/1999 | Stopped : | CONTIN |

Public Case Detail

Case Number : 155499

Data Entry Date : 26/07/2000

Hospitalisation :

Onset Date : 31/07/2000

Outcome :
Unknown

Gender : M

Weight (kg) :

Age : 19Y

DOB : 29/09/1980

Causality : Causality possible

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 : |
| Tablet | 30 Milligram Daily Oral |
| Batch : | Started : 01/01/1998 Stopped : CONTIN |

Public Case Detail

Case Number : 156659

Data Entry Date : 18/08/2000

Hospitalisation :

Onset Date : 19/06/2000

Outcome :
Unknown

Gender : M

Weight (kg) :

Age :

DOB :

Causality : Causality possible

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 : | |

Public Case Detail

Case Number : 157565

Data Entry Date : 07/09/2000

Gender : M

Hospitalisation :

Weight (kg) :

Onset Date :

Age : 12Y

Outcome :

DOB : 29/04/1988

Unknown

Causality : Causality possible

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 |

Public Case Detail

Case Number : 157696

Data Entry Date : 07/09/2000

Hospitalisation :

Onset Date : 23/08/2000

Outcome :
Recovered

Gender : M

Weight (kg) :

Age : 11Y

DOB : 23/03/1989

Causality : Causality possible

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 | Severity | Report Description | Treatment |
|------------------|----------|--------------------|---|
| Aplastic anaemia | | | Treated by bone marrow transplantation in nov 2000. |
| Pancytopenia | | | |

Medicine details :

| | |
|----------------------------|---|
| RITALIN (Suspected) | Reason : |
| Tablet | 10 Milligram Daily Oral |
| Batch : | Started : 01/04/1998 Stopped : 28/08/2000 |

Public Case Detail

Case Number : 167739

Data Entry Date : 20/08/2001
Hospitalisation : Admitted to hospital
Onset Date : 10/08/2001
Outcome :
 Recovered

Gender : M
Weight (kg) :
Age : 56Y
DOB : 08/09/1945
Causality : Causality possible

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. | |
| Electrocardiogram abnormal | | | Patient was hospitalised. treated with morphine. |
| Electrocardiogram abnormal | | | |
| Myocardial infarction | | | |

Medicine details :

| | | | |
|----------------------------|------------------|--|---------------------------------|
| ALCOHOL (Suspected) | | Reason : | |
| | | 0 | |
| Batch : | Started : | Stopped : | |
| RITALIN (Suspected) | | Reason : Behavior disorders of childhod | |
| Tablet | | 10 Milligram | Daily |
| | | | Oral |
| Batch : | Started : | L TERM | Stopped : 10/08/2001 06Y |

Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|---------------------|-------|-------------|--------|--|
| Electrocardiography | | | | Ecg showed high qrs, probable inferior infarct and st elevation. |

Public Case Detail

Case Number : 183683

Data Entry Date : 04/03/2003

Gender : M

Hospitalisation :

Weight (kg) : 35

Onset Date :

Age :

DOB : 16/10/1997

Outcome :

Causality : Causality possible

Not yet recovered

Information:

| Reaction : | | | |
|-----------------------|-----------------|---------------------------|---------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Hallucination | | Hallucinations | Ritalin was discontinued. |

| Medicine details : | | | |
|----------------------------|------------------|---|------|
| RITALIN (Suspected) | | Reason : Behavior disorders of childhood | |
| Capsule | 40 Milligram | Daily | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Case Number : 185405

Data Entry Date : 05/05/2003

Gender : M

Hospitalisation :

Weight (kg) : 35

Onset Date : 29/04/2003

Age :

DOB : 13/10/1989

Outcome :

Causality : Causality certain

Recovered

Information: Coded certain because of rechallenge.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------------------------------|---|---------------------------------------|
| Diarrhoea | Required Specialist Consultation | Acute nausea and diarrhoea within one hour of oral dose -effect lasted 4-6 hrs. Given 48 hrs off treatment and single dose repeated with same effect | none required effect passed with time |
| Nausea | Required Specialist Consultation | Acute nausea and diarrhoea within one hour of oral dose -effect lasted 4-6 hrs. Given 48 hrs off treatment and single dose repeated with same effect | none required effect passed with time |

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 | |

Public Case Detail

Case Number : 186035

Data Entry Date : 19/05/2003

Gender : M

Hospitalisation :

Weight (kg) : 20

Onset Date : 09/05/2003

Age :

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 | Severity | Report Description | Treatment |
|----------------|--------------------------|--|-----------|
| Abdominal pain | Required Visit to Doctor | Headache, nausea, abdominal pain, pale face, drowsness | |
| Headache | Required Visit to Doctor | Headache, nausea, abdominal pain, pale face, drowsness | |
| Nausea | Required Visit to Doctor | Headache, nausea, abdominal pain, pale face, drowsness | |
| Pallor | Required Visit to Doctor | Headache, nausea, abdominal pain, pale face, drowsness | |
| Somnolence | Required Visit to Doctor | Headache, nausea, abdominal pain, pale face, drowsness | |

Medicine details :

| | | | |
|------------------------------|------------------|------------------|------|
| RITALIN (Suspected) | | Reason : | |
| 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 Unspec | Daily | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Case Number : 189644

Data Entry Date : 18/08/2003

Gender : M

Hospitalisation :

Weight (kg) : 30

Onset Date : 10/08/2003

Age :

DOB : 06/01/1998

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------|--------------------------|---|-----------|
| Dyskinesia | Required Visit to Doctor | Tourettes type dyskinesias - 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 |

Public Case Detail

Case Number : 190321

Data Entry Date : 08/09/2003

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : F

Weight (kg) : 67

Age : 14Y

DOB :

Causality : Causality possible

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 :

Public Case Detail

Case Number : 192350

Data Entry Date : 19/11/2003
Hospitalisation : Admitted to hospital
Onset Date :
Outcome :
 Recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 07/01/1994
Causality : Causality possible

Information: Onset occurred approximately 4 weeks after commencing Ritalin. The patient's lower 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 |
|--------------------------------|---|--------------------|--|
| Hypertonia | Caused or prolonged inpatient hospitalisation | | Ritalin had been ceased due to the event |
| Myalgia | Caused or prolonged inpatient hospitalisation | | |
| Neuroleptic malignant syndrome | Caused or prolonged inpatient hospitalisation | | |

Medicine details :

| | |
|----------------------------|---|
| RITALIN (Suspected) | Reason : |
| | 20 Milligram Daily Oral |
| Batch : | Started : 21/10/2003 Stopped : 01/11/2003 |

Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|--------------------|---------|-------------|--------|---------|
| 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 | | | | |

Public Case Detail

Case Number : 192829

Data Entry Date : 04/12/2003

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 20/11/2003

Age : 13

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, crying, heart rate increased, confusional state, muscle twitching, dry mouth, headache, drained and quiet, body aches, fatigue. | Ratilin La has been discontinued |
| Confusional state | | | |
| Crying | | | |
| Dry mouth | | | |
| Fatigue | | | |
| Headache | | | |
| Heart rate increased | | | |
| Muscle twitching | | | |
| Pain | | | |
| Tremor | | | |

Medicine details :

| | | | |
|-------------------------------|--|-----------------------------|------|
| Ritalin LA (Suspected) | Reason : Behavior disorders of childhod | | |
| Capsule | 40 Milligram | Daily | Oral |
| Batch : | Started : 20/11/2003 | Stopped : 21/11/2003 | |

Public Case Detail

Case Number : 193009

Data Entry Date : 10/12/2003

Hospitalisation :

Onset Date : 01/09/2003

Outcome : 02/10/2003

Recovered

Gender : M

Weight (kg) : 55

Age :

DOB : 13/07/1989

Causality : Causality probable

Information:

| Reaction : | | | |
|-----------------------|--------------------------|--------------------------------|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Visual field defect | Required Visit to Doctor | Blurring of peripheral vision. | |

| Medicine details : | | | |
|----------------------------|-----------------------------|---|------|
| RITALIN (Suspected) | | Reason : Behavior disorders of childhood | |
| Tablet | 7.5 Milligram | Daily | Oral |
| Batch : | Started : 05/04/2003 | Stopped : 19/09/2003 | |

Public Case Detail

Case Number : 193329

Data Entry Date : 18/12/2003

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99U

Outcome :

DOB :

Unknown

Causality : Causality possible

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 :

Public Case Detail

Case Number : 193410

Data Entry Date : 22/12/2003

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

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

Public Case Detail

Case Number : 193412

Data Entry Date : 22/12/2003

Hospitalisation :

Onset Date :

Outcome :

Not yet recovered

Gender : F

Weight (kg) : 0

Age : 99U

DOB :

Causality : Causality possible

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 | |

Public Case Detail

Case Number : 193415

Data Entry Date : 22/12/2003

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 10/08/2003

Age : 16Y

DOB :

Outcome :

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 | |

Public Case Detail

Case Number : 195056

Data Entry Date : 01/03/2004

Hospitalisation :

Onset Date : 29/01/2004

Outcome :
Recovered

Gender : M

Weight (kg) : 0

Age : 6Y

DOB :

Causality : Causality probable

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 |

Public Case Detail

Case Number : 199772

Data Entry Date : 06/08/2004

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/05/2004

Age :

DOB : 31/10/1995

Outcome :

Causality : Causality possible

Recovered

Information:

| Reaction : | | | |
|-----------------------|-----------------|---------------------------|------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Drug ineffective | | Lack of effect with drug. | Changed to Ritalin LA. |

| Medicine details : | | | |
|----------------------------|-----------------------------|---|------|
| RITALIN (Suspected) | | Reason : Behavior disorders of childhood | |
| | 20 Milligram | Daily | Oral |
| Batch : B3524 | Started : 01/11/2003 | Stopped : | 0 |

Public Case Detail

Case Number : 199877

Data Entry Date : 11/08/2004

Hospitalisation :

Onset Date : 15/05/2004

Outcome :
Recovered

Gender : M

Weight (kg) : 0

Age :

DOB : 31/10/1995

Causality : Causality possible

Information: 199772 is a duplicate.

| Reaction : | | | |
|-----------------------|----------------------------------|--|---|
| Preferred Term | Severity | Report Description | Treatment |
| Arrhythmia | Required Specialist Consultation | Patient experienced arrhythmia, tachycardia, dizziness and drug ineffective. | ECG performed. Changed back to Ritalin. |
| 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 |

Public Case Detail

Case Number : 201684

Data Entry Date : 13/10/2004

Hospitalisation :

Onset Date : 22/04/2004

Outcome : 25/04/2004

Recovered

Gender : U

Weight (kg) : 0

Age : 99U

DOB :

Causality : Causality possible

Information:

| Reaction : | | | |
|--------------------------|-----------------|---------------------------------------|--------------------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Ventricular fibrillation | | Ventric fibrillation, cardiac arrest. | NB: Ritalin LA used. Ritalin ceased. |
| Cardiac arrest | | | |

| Medicine details : | | | |
|----------------------------|-----------------------------|--------|------------------------------------|
| RITALIN (Suspected) | Reason : | | |
| | 60 Milligram | Daily | Oral |
| Batch : | Started : 17/03/1995 | L TERM | Stopped : 22/04/2004 0 |

Public Case Detail

Case Number : 202677

Data Entry Date : 18/11/2004

Hospitalisation :

Onset Date : 15/10/2004

Outcome :
Recovered

Gender : F

Weight (kg) : 0

Age : 13

DOB :

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|---|--|
| Preferred Term | Severity | Report Description | Treatment |
| Urticaria | | Patient experienced an urticaria rash within 24 hours of commencing Ritalin LA. | Ritalin LA ceased. Antihistamines given. |

| Medicine details : | | | |
|-------------------------------|-----------------------------|------------------|------|
| Ritalin LA (Suspected) | | Reason : | |
| Capsule | 30 Milligram | Daily | Oral |
| Batch : | Started : 15/10/2004 | Stopped : | |

Public Case Detail

Case Number : 202887

Data Entry Date : 19/11/2004

Hospitalisation : Admitted to hospital

Onset Date :

Outcome :
Unknown

Gender : U

Weight (kg) : 22.6

Age :

DOB : 30/07/1997

Causality : Causality possible

Information:

| Reaction : | | | |
|-------------------------------|---|---|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Anxiety | Caused or prolonged inpatient hospitalisation | Patient developed significant anxiety and OCD symptoms. | |
| Obsessive-compulsive disorder | Caused or prolonged inpatient hospitalisation | | |

| Medicine details : | | | |
|--|-----------------------------|---|------|
| DEXAMPHEMINE SULPHATE (Suspected) | | Reason : Behavior disorders of childhood | |
| | 10 Milligram | Daily | |
| Batch : | Started : 15/04/2004 | Stopped : 15/06/2004 | |
| RITALIN (Suspected) | | Reason : Behavior disorders of childhood | |
| | 10 Milligram | Daily | Oral |
| Batch : | Started : 15/07/2004 | Stopped : 15/09/2004 | |

Public Case Detail

Case Number : 203217

Data Entry Date : 01/12/2004

Hospitalisation :

Onset Date : 15/05/2004

Outcome :

Not yet recovered

Gender : M

Weight (kg) : 0

Age :

DOB : 15/08/1988

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|--------------------------|--|-----------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Retinal pigmentation | Required Visit to Doctor | Macula: abnormal pigmentary granulation of both maculae. | Investigated, no treatment. |

| Medicine details : | | | |
|--|------------------|--------------------------------------|--------------------------|
| DEXAMPHEMINE SULPHATE (Suspected) | | Reason : Unspecified neurosis | |
| Batch : | Started : | L TERM | Stopped : |
| RITALIN (Suspected) | | Reason : Unspecified neurosis | |
| Batch : | Started : | L TERM | Stopped : Oral |

Public Case Detail

Case Number : 203371

Data Entry Date : 08/12/2004

Hospitalisation :

Onset Date : 15/08/2004

Outcome :
Recovered

Gender : M

Weight (kg) : 0

Age : 8Y

DOB :

Causality : Causality probable

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 | 20 Milligram | Daily | Oral |
| Batch : | Started : 15/08/2004 | Stopped : 30/08/2004 | 0 |

Public Case Detail

Case Number : 203398

Data Entry Date : 09/12/2004

Hospitalisation :

Onset Date : 27/09/2004

Outcome :
Recovered

Gender : M

Weight (kg) : 75

Age :

DOB : 13/03/1992

Causality : Causality possible

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------|----------|---|--|
| Withdrawal syndrome | | Withdrawal state from taking Ritalin LA which lasted a week. Symptoms 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. | Parents didn't seek medical advice regarding this reaction |
| Visual disturbance | | distortions (objects varying in size), | |
| Affect lability | | | |
| Hallucination, visual | | | |
| Headache | | | |
| Hyperhidrosis | | | |
| Nervousness | | | |
| Vomiting | | | |

Medicine details :

| | |
|-------------------------------|---|
| Ritalin LA (Suspected) | Reason : |
| Capsule | 60 Milligram Daily Oral |
| Batch : | Started : 16/06/2003 Stopped : 27/09/2004 |

Public Case Detail

Case Number : 205291

Data Entry Date : 16/02/2005

Hospitalisation :

Onset Date : 04/02/2005

Outcome :

Not yet recovered

Gender : M

Weight (kg) : 60

Age :

DOB : 05/02/1992

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|--------------------------|---|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Lethargy | Required Visit to Doctor | The patient experienced 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 : | |

Public Case Detail

Case Number : 206162

Data Entry Date : 17/03/2005

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/01/2005

Age :

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. | |
| Visual disturbance | | | |

| Medicine details : | | | |
|-------------------------------|-----------------------------|---|------------------|
| Ritalin LA (Suspected) | | Reason : Behavior disorders of childhood | |
| Capsule | 20 Milligram | Daily | Oral |
| Batch : | Started : 15/09/2003 | L TERM | Stopped : |

Public Case Detail

Case Number : 206905

Data Entry Date : 11/04/2005

Hospitalisation :

Onset Date : 24/02/2005

Outcome :
Not yet recovered

Gender : M

Weight (kg) : 0

Age :

DOB : 14/11/1997

Causality : Causality possible

Information:

| Reaction : | | | |
|---------------------------|-----------------------|---|--|
| Preferred Term | Severity | Report Description | Treatment |
| Abnormal behaviour | Incapacity/disability | Uncontrollable, suddenly with dangerous behaviours, hyperactive and drug ineffective. | Zoloft given in an increased dose as a result of the events. |
| 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 | |

Public Case Detail

Case Number : 207373

Data Entry Date : 22/04/2005

Hospitalisation :

Onset Date : 15/12/2004

Outcome :

Not yet recovered

Gender : M

Weight (kg) : 0

Age : 11Y

DOB :

Causality : Causality possible

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. | He was decreased back to Ritalin LA 20mg/day. |
| Hallucination | | | |
| Therapy regimen changed | | | |

Medicine details :

| | | | |
|-------------------------------|------------------|------------------|------|
| Ritalin LA (Suspected) | Reason : | | |
| Capsule | 40 Milligram | Daily | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Case Number : 209343

Data Entry Date : 30/06/2005

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 08/06/2005

Age : 11Y

Outcome :

DOB :

Unknown

Causality : Causality possible

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 : | |

Public Case Detail

Case Number : 209472

Data Entry Date : 05/07/2005

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : M

Weight (kg) : 0

Age : 99u

DOB :

Causality : Causality possible

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|--|-----------|
| Weight increased | | 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 : |
| | Stopped : |

Public Case Detail

Case Number : 209473

Data Entry Date : 05/07/2005

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

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 previously taking Methylphenidate 10mg tablets without weight gain. | |

Medicine details :

| | | |
|-------------------------------|------------------|------------------|
| Ritalin LA (Suspected) | Reason : | |
| Capsule | | Oral |
| Batch : | Started : | Stopped : |

Public Case Detail

Case Number : 209474

Data Entry Date : 05/07/2005

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

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 : |

Public Case Detail

Case Number : 210896

Data Entry Date : 18/08/2005

Hospitalisation :

Onset Date : 15/07/2005

Outcome :
Unknown

Gender : M

Weight (kg) : 0

Age : 12Y

DOB :

Causality : Causality possible

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 : |

Public Case Detail

Case Number : 211209

Data Entry Date : 30/08/2005

Hospitalisation :

Onset Date :

Outcome :

Recovered

Gender : F

Weight (kg) : 0

Age : 99u

DOB :

Causality : Causality possible

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

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------|----------|---|-----------------|
| 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'. | Ritalin ceased. |
| Anorexia | | | |
| Insomnia | | | |
| Nausea | | | |
| Social avoidant behaviour | | | |

Medicine details :

| | |
|----------------------------|---|
| RITALIN (Suspected) | Reason : Behavior disorders of childhood |
| Tablet | 0.5 Dose Unspec Daily Oral |
| Batch : | Started : |
| | Stopped : |

Public Case Detail

Case Number : 211693

Data Entry Date : 15/09/2005

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 35

Onset Date : 24/07/2005

Age : 5Y

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|---|---|
| Preferred Term | Severity | Report Description | Treatment |
| Urticaria | | The child developed urticaria and angioedema. | Treated with antihistamine, Ritalin ceased. |
| Angioedema | | | |

| Medicine details : | | | |
|----------------------------|-----------------------------|-----------------------------|------|
| RITALIN (Suspected) | | Reason : | |
| | 20 Milligram | Daily | Oral |
| Batch : | Started : 10/07/2005 | Stopped : 29/07/2005 | |

Public Case Detail

Case Number : 211853

Data Entry Date : 22/09/2005

Hospitalisation :

Onset Date : 21/08/2005

Outcome :
Recovered

Gender : M

Weight (kg) : 0

Age : 17Y

DOB :

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------------|---|--|
| Preferred Term | Severity | Report Description | Treatment |
| Somnolence | Incapacity/disability | Patient experienced drowsiness on 21 Aug 2005, approximately 2 weeks after being switched from Attenta. | Ritalin was changed from 10mg 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 : | |

Public Case Detail

Case Number : 212269

Data Entry Date : 06/10/2005

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : U

Weight (kg) : 0

Age : 99u

DOB :

Causality : Causality possible

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 : | |

Public Case Detail

Case Number : 215535

Data Entry Date : 03/02/2006

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : M

Weight (kg) : 0

Age : 23Y

DOB :

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|--|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Tachycardia | | The patient experienced episodic tachycardia of 140 bpm. | |

| Medicine details : | | | |
|----------------------------|------------------|------------------|------|
| RITALIN (Suspected) | | Reason : | |
| | 30 Milligram | Daily | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Case Number : 215892

Data Entry Date : 16/02/2006

Hospitalisation :

Onset Date : 31/01/2006

Outcome :
Unknown

Gender : M

Weight (kg) : 0

Age : 28Y

DOB :

Causality : Causality possible

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 he had a hallucination. | |
| Irritability | | | |
| Sleep disorder | | | |

Medicine details :

| | | | |
|----------------------------|-----------------------------|--|------|
| RITALIN (Suspected) | | Reason : Behavior disorders of childhod | |
| Tablet | 30 Milligram | Daily | Oral |
| Batch : | Started : 31/01/2006 | Stopped : | 0 |

Public Case Detail

Case Number : 216810

Data Entry Date : 31/03/2006

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/04/1995

Age :

DOB : 13/01/1984

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|------------------------------|-----------|
| Tic | | Patient developed motor tics | |

Medicine details :

| | |
|---------------------|---|
| RITALIN (Suspected) | Reason : Behavior disorders of childhood |
| Batch : | Started : 07/03/1995 |
| | Stopped : 15/06/1995 |

Public Case Detail

Case Number : 217768

Data Entry Date : 28/04/2006

Hospitalisation :

Onset Date : 13/04/2006

Outcome :
Unknown

Gender : M

Weight (kg) : 0

Age :

DOB : 06/02/1999

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|--|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Pruritus | | Patient experienced intense itchiness. | Ritalin ceased. |

| Medicine details : | | | |
|----------------------------|-----------------------------|-----------------------------|------|
| RITALIN (Suspected) | | Reason : | |
| Tablet | 10 Milligram | Daily | Oral |
| Batch : | Started : 13/04/2006 | Stopped : 13/04/2006 | 0 |

Public Case Detail

Case Number : 217907

Data Entry Date : 02/05/2006

Hospitalisation :

Onset Date :

Outcome :
Unknown

Gender : U

Weight (kg) : 0

Age : 99U

DOB :

Causality : Causality possible

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 : | |

Public Case Detail

Case Number : 217971

Data Entry Date : 04/05/2006

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : M

Weight (kg) : 0

Age : 14Y

DOB :

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|--|---------------------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Vision blurred | | Patient complained of experiencing blurred vision. | Requested to have an eye examination. |

| Medicine details : | | | |
|----------------------------|------------------|------------------|------|
| RITALIN (Suspected) | Reason : | | |
| | 50 Milligram | Daily | Oral |
| Batch : | Started : | Stopped : | 0 |

Public Case Detail

Case Number : 218030

Data Entry Date : 05/05/2006

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 28Y

Outcome :

DOB :

Unknown

Causality : Causality possible

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

Public Case Detail

Case Number : 218894

Data Entry Date : 03/06/2006

Hospitalisation :

Onset Date : 14/05/2006

Outcome :
Recovered

Gender : F

Weight (kg) : 0

Age :

DOB : 16/07/1981

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|---|---|
| Preferred Term | Severity | Report Description | Treatment |
| Drug interaction | | Suspected drug interaction: After commencing Ritalin (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 occurring within an hour of Seroquel dosing; and difficulty waking up in the morning followed by a "hangover" effect during the day. | Decreased dose of Seroquel from 50mg to 25mg. |
| Somnolence | | | |

| Medicine details : | | | |
|-------------------------------|-----------------------------|------------------|------|
| RITALIN (Interaction) | | | |
| Tablet | 30 Milligram | Daily | Oral |
| Batch : B5052 | Started : 28/04/2006 | Stopped : | |
| SEROQUEL (Interaction) | | | |
| Tablet | 50 Milligram | Daily | Oral |
| Batch : CX 371 | Started : 15/03/2006 | Stopped : | |
| EFEXOR (Other drug) | | | |
| Capsule | 300 Milligram | Daily | Oral |
| Batch : 70161A | Started : | Stopped : | |

Public Case Detail

Case Number : 219297

Data Entry Date : 20/06/2006

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : M

Weight (kg) : 0

Age : 12Y

DOB :

Causality : Causality possible

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 : | |
| | | | |

Public Case Detail

Case Number : 219446

Data Entry Date : 23/06/2006

Hospitalisation :

Onset Date : 02/11/2005

Outcome :
Unknown

Gender : M

Weight (kg) : 35

Age :

DOB : 31/08/1995

Causality : Causality possible

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 : |

Public Case Detail

Case Number : 220231

Data Entry Date : 20/07/2006

Gender : M

Hospitalisation :

Weight (kg) : 60

Onset Date : 19/05/2006

Age :

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 Methylphenidate for ADHD. Responding very well to this treatment. Initiated on Roaccutane for coexisting severe acne. Within 1-2 weeks symptoms of ADHD returned despite ongoing complaint 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. | Ceased Roaccutane |

Drug effect decreased

Medicine details :

| | |
|---------------------------------|---|
| RITALIN (Interaction) | Reason : Behavior disorders of childhood |
| Capsule | 40 Milligram Daily Oral |
| Batch : | Started : 18/09/2005 Stopped : |
| ROACCUTANE (Interaction) | Reason : Other acne of sebaceous glands |
| Capsule | 10 Milligram Daily Oral |
| Batch : | Started : 20/03/2006 Stopped : 22/05/2006 |

Public Case Detail

Case Number : 220887

Data Entry Date : 18/08/2006

Hospitalisation :

Onset Date : 14/07/2006

Outcome :
Recovered

Gender : F

Weight (kg) : 31

Age :

DOB : 02/02/1995

Causality : Causality certain

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 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. | Ritalin withdrawn. |
| Pain in jaw | | | |
| Pruritus | | | |
| Swelling | | | |

Medicine details :

| | | | |
|---------------------------------|-----------------------------|--|------|
| RITALIN (Suspected) | | Reason : Behavior disorders of childhod | |
| Tablet | 5 Milligram | 2 times | Oral |
| Batch : D5051 exp 7/2007 | Started : 14/07/2006 | Stopped : 17/08/2006 | 0 |

Public Case Detail

Case Number : 222921

Data Entry Date : 07/11/2006

Hospitalisation :

Onset Date : 01/07/2006

Outcome :
Unknown

Gender : M

Weight (kg) : 0

Age :

DOB : 07/02/1997

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|------------------------------|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Neoplasm malignant | | Dorsal coccygeal ependymoma. | |

| Medicine details : | | | |
|----------------------------|-----------------------------|------------------|------|
| RITALIN (Suspected) | Reason : | | |
| Capsule | 20 Milligram | Daily | Oral |
| Batch : | Started : 01/05/2006 | Stopped : | 0 |

Public Case Detail

Case Number : 223299

Data Entry Date : 17/11/2006

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 05/10/2006

Age :

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. | |
| Pharmaceutical product complaint | | | |

Medicine details :

| | | | |
|-------------------------------|---|------------------|------|
| Ritalin LA (Suspected) | Reason : Behavior disorders of childhood | | |
| Capsule | 30 Milligram | Daily | Oral |
| Batch : F4077 | Started : 15/09/2006 | Stopped : | 0 |

Public Case Detail

Case Number : 224178

Data Entry Date : 19/12/2006

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 16/10/2006

Age : 60Y

Outcome : 11/11/2006

DOB :

Recovered

Causality : Causality possible

Information: SUSPECTED INTERACTION

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|--------------------|----------|--|----------------------|
| Agitation | | Since starting Inner health, patient is restless and excessively stimulated, wakes at 5.30am (prev 7am). Restless with increase distractability and decreased concentration. | Ceased Inner Health. |
| 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 : |

Public Case Detail

Case Number : 224469

Data Entry Date : 09/01/2007

Hospitalisation : Required a visit to the doctor

Onset Date :

Outcome :
Unknown

Gender : M

Weight (kg) : 0

Age : 99U

DOB :

Causality : Causality possible

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 : | |
| Capsule | 30 Milligram | Daily | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Case Number : 226800

Data Entry Date : 21/03/2007

Hospitalisation :

Onset Date : 12/02/2007

Outcome : 12/02/2007

Recovered

Gender : M

Weight (kg) : 0

Age :

DOB : 30/09/1975

Causality : Causality possible

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 | Treatment |
|----------------------------|----------|---|-----------|
| Lack of spontaneous speech | | Patient stated that within a 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 several hours later. | |
| 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 :

Public Case Detail

Case Number : 226867

Data Entry Date : 22/03/2007

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : M

Weight (kg) : 0

Age : 99U

DOB :

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|---------------------------|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Tic | | Patient developed a tic. | |

| Medicine details : | | | |
|-------------------------------|------------------|----------------------|------|
| Ritalin LA (Suspected) | | Reason : | |
| Capsule | | 1 Dose Unspec Weekly | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Case Number : 228378

Data Entry Date : 10/05/2007

Hospitalisation :

Onset Date : 18/03/2007

Outcome :
Recovered

Gender : M

Weight (kg) : 0

Age :

DOB : 02/06/1967

Causality : Causality probable

Information:

| Reaction : | | | |
|------------------------|-----------------|---|------------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Mass | | Patient reported that Ritalin would only last 45 minutes then the effect would "drop off" and he would experience muscle pain, hot sweats, tightness in the chest and stomach area, nausea and lumps in the arms below the elbow. | Dose decreased then stopped. |
| Abdominal discomfort | | | |
| Chest discomfort | | | |
| Drug effect decreased | | | |
| Hyperhidrosis | | | |
| Muscle twitching | | | |
| Myalgia | | | |
| Nausea | | | |
| Pain | | | |
| Palpitations | | | |
| Pharyngolaryngeal pain | | | |
| Polydipsia | | | |
| Polyuria | | | |
| Pyrexia | | | |

Medicine details :

| | | | |
|----------------------------|-----------------------------|--|------|
| RITALIN (Suspected) | | Reason : Cataplexy&narcolepsy brain dis | |
| Tablet | 60 Milligram | Daily | Oral |
| Batch : | Started : 18/03/2007 | Stopped : 22/03/2007 | 0 |

Public Case Detail

Case Number : 229056

Data Entry Date : 30/05/2007

Hospitalisation :

Onset Date : 15/02/2007

Outcome :
Unknown

Gender : M

Weight (kg) : 0

Age : 8Y

DOB :

Causality : Causality possible

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 gastroenterologist. |
| Duodenal scarring | | | |
| Vomiting | | | |
| Weight decreased | | | |

| Medicine details : | | | |
|----------------------------|------------------|--------|------------------|
| RITALIN (Suspected) | Reason : | | |
| Tablet | 10 Milligram | Daily | Oral |
| Batch : | Started : | L TERM | Stopped : |

| Laboratory Investigations : | | | | |
|------------------------------------|--------------|--------------------|---------------|----------------|
| Type | Range | Date Tested | Result | Details |
| Endoscopy | | | | |

Public Case Detail

Case Number : 229120

Data Entry Date : 30/05/2007

Hospitalisation :

Onset Date :

Outcome :

Recovered

Gender : M

Weight (kg) : 0

Age : 11Y

DOB :

Causality : Causality possible

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. | Ceased medication. |
| Depression | | | |
| Drug ineffective | | | |

| Medicine details : | | | |
|------------------------------|------------------|--|--|
| RITALIN (Suspected) | | Reason : Behavior disorders of childhod | |
| Batch : | Started : | Stopped : | |
| Strattera (Suspected) | | Reason : Behavior disorders of childhod | |
| Capsule | | Oral | |
| Batch : | Started : | Stopped : | |

Public Case Detail

Case Number : 229750

Data Entry Date : 14/06/2007

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 80

Onset Date : 15/11/2006

Age :

DOB : 28/03/1992

Outcome :
Recovered

Causality : Causality possible

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---------------------|----------|--|-----------------|
| Rash | | Patient experienced rash 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. | Ceased Ritalin. |
| 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 : |

Public Case Detail

Case Number : 230028

Data Entry Date : 21/06/2007

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : M

Weight (kg) : 0

Age : 11Y

DOB :

Causality : Causality possible

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 : | |

Public Case Detail

Case Number : 231283

Data Entry Date : 27/07/2007

Hospitalisation :

Onset Date : 30/06/2007

Outcome :
Recovered

Gender : M

Weight (kg) : 25

Age :

DOB : 05/12/1999

Causality : Causality probable

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 : | |

Public Case Detail

Case Number : 233136

Data Entry Date : 06/09/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

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 : | |

Public Case Detail

Case Number : 234040

Data Entry Date : 05/10/2007

Hospitalisation :

Onset Date :

Outcome : 27/08/2007

Recovered

Gender : M

Weight (kg) : 11.7

Age :

DOB : 07/08/2003

Causality : Causality possible

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------|------------------|---|------------------------------------|
| Stevens-Johnson syndrome | Life threatening | Child experienced more 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. | Stopped carbamazepine and ritalin. |
| Conjunctivitis | Life threatening | | |
| Cough | Life threatening | | |
| Diarrhoea | Life threatening | | |
| Face oedema | 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 |

Public Case Detail

Case Number : 234956

Data Entry Date : 01/11/2007

Hospitalisation :

Onset Date :

Outcome :
Unknown

Gender : U

Weight (kg) : 0

Age : 99U

DOB :

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|--|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Psychiatric symptom | | 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 : | |

Public Case Detail

Case Number : 238430

Data Entry Date : 29/02/2008

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : F

Weight (kg) : 0

Age : 99u

DOB :

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|---|-----------------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Cardiomyopathy | | Patient experienced cardiomyopathy whilst on Ritalin. | Ritalin ceased then reintroduced. |

| Medicine details : | | | |
|----------------------------|------------------|------------------|--|
| RITALIN (Suspected) | | Reason : | |
| Batch : | Started : | Stopped : | |

Public Case Detail

Case Number : 238798

Data Entry Date : 11/03/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 14/01/2008

Age :

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", regularly 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 : |

Public Case Detail

Case Number : 239067

Data Entry Date : 18/03/2008

Hospitalisation :

Onset Date : 19/02/2008

Outcome :
Not yet recovered

Gender : M

Weight (kg) : 0

Age :

DOB : 04/02/1995

Causality : Causality possible

Information: Patient is also epileptic.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|--|-----------|
| Coma | | <p>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.</p> | |
| Confusional state | | | |
| Dyskinesia | | | |
| Eye pain | | | |
| Formication | | | |
| Heart rate increased | | | |

| Reaction : | | | |
|-----------------------|-----------------|---------------------------|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Hyperhidrosis | | | |
| 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 |

Public Case Detail

Case Number : 239404

Data Entry Date : 31/03/2008

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : M

Weight (kg) : 0

Age : 99U

DOB :

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|--|------------------|
| 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 : | |

Public Case Detail

Case Number : 239999

Data Entry Date : 15/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

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 angry and upset, self mutilation. 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 :

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