

Case Number: 26044

Gender: M

**Data Entry Date**: 24/09/1981 **Weight (kg)**: 85

Hospitalisation: Age: 65Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information: see original report for

drugs taken concurrently with suspected drug. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month, the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during

the month.

Reaction:

Preferred Term Severity Report Description Treatment

Dry mouth Withdrawal of dexamphetamine

sulphate.

Stomatitis

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)**Reason: Obesity other than endoc origin

30 Milligram Daily

**Batch**: **Started**: 01/02/1981 **Stopped**: 28/08/1981

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Case Number: 38758

 $\textbf{Gender}: \ M$ 

**Data Entry Date**: 20/06/1985

Weight (kg):

**Hospitalisation:** 

3 . ( 3)

Onset Date: 12/10/1982

**Age**: 10Y

Outcome :

DOB:

Not yet recovered

Causality: Causality possible

Information:

Reaction:

Preferred Term

Severity

**Report Description** 

**Treatment** 

Muscle twitching

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected)

Reason: Behavior disorders of childhod

Tablet

5 Milligram

Daily

Oral

Batch:

Started: 29/07/1981

Stopped:

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Case Number: 72594 Gender: U

Data Entry Date: 28/08/1991 Weight (kg):

Hospitalisation : Age :

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Psychotic disorder

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

Tablet 15 Milligram Daily Oral

**Batch**: **Started**: 30/04/1991 **Stopped**: 05/08/1991

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Case Number: 81018

Gender: M

**Data Entry Date**: 19/11/1992 **Weight (kg)**: 74

Hospitalisation: Age: 59Y

**Onset Date**: 17/11/1992 **DOB**:

Outcome: Causality: Causality certain

Recovered

Information: Drug was readministered aproximately 10 min later with same effect to a slightly lesser

degree.

Reaction:

Preferred Term Severity Report Description Treatment

Pruritus Severe Itching all over body.

Paraesthesia Severe Skin burning all over body.

**Medicine details:** 

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

Injection 124 Milligram 1 time Intravenous

**Batch**: **Started**: 17/11/1992 **Stopped**:

MAXOLON (Other drug) Reason :

Injection 10 Milligram Daily Intravenous

Batch: Started: 17/11/1992 Stopped:

STEMETIL (Other drug) Reason:

Injection 12.5 Milligram Daily Intravenous

Batch: Started: 17/11/1992 Stopped:

ZOFRAN (Other drug) Reason :

Injection 8 Milligram Daily Intravenous

Batch: Started: 17/11/1992 Stopped:

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Case Number: 85199 Gender: M

**Data Entry Date**: 09/06/1993 **Weight (kg)**: 20

**Hospitalisation**: Age: 05Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Depression Paranoia

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

0

Batch: Started: Stopped:

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Case Number: 91885

Gender: M

**Data Entry Date**: 30/03/1994 **Weight (kg)**: 20

Hospitalisation: Age: 06Y

**Onset Date**: 17/03/1994 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

**Information:** Developed tourette's syndrome.

Reaction:

Preferred Term Severity Report Description Treatment

Muscle twitching

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

7.5 Milligram Total

**Batch: Started:** 16/03/1994 **Stopped:** 17/03/1994

PUSIME02 Page 6 of 65



Case Number: 97215

Gender: M

**Data Entry Date**: 21/11/1994 **Weight (kg)**: 22

Hospitalisation: Age: 6Y

**Onset Date**: 04/11/1994 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dyskinesia

Muscle twitching

**Medicine details:** 

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

2.5 Milligram Daily

**Batch**: **Started**: 24/09/1994 **Stopped**: 07/11/1994

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Case Number: 97571

Gender: M

**Data Entry Date**: 07/12/1994

Weight (kg): 54

**Hospitalisation:** 

**Age:** 16Y

\_

Onset Date: 27/10/1994 DOB:

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Asthenia

Convulsion

Electroencephalogram

abnormal

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason:

Tablet

10 Milligram

5 Milligram

Daily

Oral

Batch :

Started: 22/09/1994

**Stopped**: 27/10/1994

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason:

Tablet

1 15/00/1001

Daily

Oral

Batch :

**Started:** 15/09/1994

Stopped:

**Laboratory Investigations:** 

Type Range

Electroencephalograph

Date Tested Result

Details

Eeg post seizure showed definite

epileptiform activity.

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Case Number: 99607

Gender: M

**Data Entry Date**: 16/03/1995 **Weight (kg)**: 75

Hospitalisation: Age: 14Y

**Onset Date**: 15/01/1995 **DOB**:

Outcome: Causality: Causality possible

Recovered

Information: S.a.h. occurred during water skiing and put douwn to trauma

Reaction:

Preferred Term Severity Report Description Treatment

Subarachnoid haemorrhage

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

Tablet 15 Milligram Daily Oral

Batch: Started: L TERM Stopped: 15/01/1995

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**Case Number : 106683** 

Gender: M

**Data Entry Date**: 26/02/1996

Weight (kg):

Hospitalisation:

**Age:** 18Y

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 start date is not accurate but indicates that start occurred

sometime during the year.

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Therapeutic response

decreased

Tablet

Medicine details:

**DEXAMPHETAMINE SULPHATE (Interaction)** 

Reason:

Daily

Oral

Batch:

**Started**: 01/01/1986

Stopped :

**MINOMYCIN** (Interaction)

Reason: Other acne of sebaceous glands

0

15 Milligram

Batch:

Started: 01/01/1995

Stopped:

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**Case Number: 110758** 

Gender: M

**Data Entry Date**: 13/08/1996 **Weight (kg)**: 28

Hospitalisation: Age: 6Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information: Child with attention deficit hyperactivity disorder. the dosage start date is not

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

sometime during the month.

Reaction:

Preferred Term Severity Report Description Treatment

Insomnia

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)**Reason: Behavior disorders of childhod

5 Milligram Daily

**Batch: Started:** 01/06/1993 **Stopped:** 28/08/1993

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**Case Number: 112816** 

Gender: M

**Data Entry Date**: 01/11/1996 **Weight (kg)**: 20

Hospitalisation: Age: 8Y

**Onset Date**: 05/08/1996 **DOB**: 27/05/1988

Outcome: Causality: Causality probable

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Aggression Rage attacks.

Headache Severe

Nervousness

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

5 Milligram Daily

**Batch**: **Started**: 04/08/1996 **Stopped**: 12/08/1996

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**Case Number: 113842** 

Gender: F

**Data Entry Date:** 13/12/1996

Weight (kg): 55

**Hospitalisation:** 

**Age:** 15Y

Onset Date: 28/08/1996

DOB:

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

**Preferred Term** 

**Report Description** 

Daily

**Treatment** 

Painful blue and cold hands.

Medicine details:

Peripheral ischaemia

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason:

**Stopped**: 28/08/1996

**LOGYNON ED (Other drug)** 

Reason: Painful menstruation

1 Dose Unspec Daily

15 Milligram

Batch:

Batch:

Started:

Severity

Started:

CONTIN

**NAPROXEN (Other drug)** 

Reason: Other disturbance of sensation 500 Milligram Daily

Batch:

Started: 21/08/1996

Stopped:

Stopped:

CONTIN

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Case Number: 114975

**Data Entry Date**: 04/02/1997 **Weight (kg)**: 35

**Hospitalisation**: Age: 10Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Abdominal pain

Anorexia

**Medicine details:** 

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

Tablet 0 Oral

Batch : Started : Stopped :

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**Case Number : 116910** 

 $\textbf{Gender}: \ M$ 

**Data Entry Date**: 18/04/1997

Weight (kg):

**Hospitalisation:** 

Age: 7Y

Onset Date: 15/04/1997

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

**Preferred Term** 

Severity Report Description

**Treatment** 

Chills

Tremor

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason:

Tablet

3 Dose Unspec Daily Oral

Batch: Started: Stopped:

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**Case Number: 117240** 

Gender: F

**Data Entry Date**: 05/05/1997 **Weight (kg)**: 47

Hospitalisation: Age: 12Y

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

Outcome: Causality: Causality certain

Recovered

Information: Symptoms returned on rechallenge with smaller dose of 2.5 mg.

Reaction:

Preferred Term Severity Report Description Treatment

Rash erythematous Rash on lower limbs.

**Pruritus** 

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

Tablet 10 Milligram Daily Oral

**Batch**: **Started**: 05/04/1997 **Stopped**: 08/04/1997

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Case Number: 118611 Gender: M

Data Entry Date: 30/06/1997 Weight (kg):

Hospitalisation: Age: A4

**Onset Date**: 31/12/1997 **DOB**:

Outcome : Causality : Causality possible

Unknown

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

the year.

Reaction:

Preferred Term Severity Report Description Treatment

Drug ineffective "dexamphetamine didn't work with norvasc"

Medicine details:

DEXAMPHETAMINE SULPHATE (Interaction) Reason :

Tablet 20 Milligram Daily Oral

Batch: Started: Stopped:

NORVASC (Interaction) Reason: Essential benign hypertension

Tablet 2.5 Milligram Daily Oral

Batch: Started: Stopped:

RAMACE (Interaction) Reason: Essential benign hypertension

Tablet 10 Milligram Daily Oral

Batch: Started: Stopped:

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**Case Number: 125344** 

Gender: U

Age: AC

**Data Entry Date**: 26/02/1998

Weight (kg):

Hospitalisation: Admitted to hospital

Admitted to be enited

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information: The event resolved within 24 hour and dexamphetamine recommenced.

Reaction:

Preferred Term Severity Report Description Treatment

Hyperkinesia Hyperstimulation

Agitation Zoloft and dexamphetamine

ceased.

Agitation

Nervousness

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)**Reason: Behavior disorders of childhod

Oral application 0 Oral

Batch: Started: Stopped:

ZOLOFT (Suspected) Reason: Behavior disorders of childhod

Tablet 25 Milligram Daily Oral

Batch: Started: Stopped:

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**Case Number: 125348** 

Gender: U

**Data Entry Date**: 26/02/1998

Weight (kg):

Hospitalisation: Admitted to hospital

Age: AC

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Recovered

Information: The event resolved within 24 hrs and dexamphetamine recommenced.

Reaction:

Preferred Term Severity Report Description Treatment

Hyperkinesia Hyperstimulation

Agitation Zoloft and dexamphetamine

ceased

Agitation

Nervousness

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason : Alcoholism

Oral application 0 Oral

Batch: Started: Stopped:

ZOLOFT (Suspected) Reason : Alcoholism

Tablet 25 Milligram Daily Oral

Batch: Started: Stopped:

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**Case Number: 128504** 

Gender: M

**Data Entry Date**: 18/06/1998 **Weight (kg)**: 75

Hospitalisation: Age: 48Y

Onset Date: 03/06/1998 DOB: 09/08/1949

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

Myalgia Neuralgia

Neutropenia Dexamphetamine and orudis

ceased

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

Tablet 15 Milligram Daily Oral

**Batch: Started:** 01/05/1998 **Stopped:** 07/06/1998

ORUDIS SR (Suspected) Reason : Otr&unsp vertebrogen pain synd

100 Milligram Daily

Batch: Started: 02/06/1998 Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

 Haemoglobin
 05/06/1998
 156

 Platelets
 05/06/1998
 178

 White blood cells
 05/06/1998
 2.8

 Lymphocytes
 05/06/1998
 1.18

 Neutrophils
 05/06/1998
 0.49

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**Case Number: 135095** 

Gender: F

**Data Entry Date**: 14/01/1999 **Weight (kg)**: 50

Hospitalisation: Age: 13Y

**Onset Date**: 15/10/1998 **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

Alopecia Worsening of a bald spot

on top of head.

Medicine details:

AROPAX (Suspected) Reason : Depression

1 Dose Unspec Daily

Batch: Started: 11/06/1998 Stopped: CONTIN

DEXAMPHETAMINE SULPHATE (Suspected) Reason: Behavior disorders of childhod

3 Dose Unspec Daily

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

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**Case Number: 136646** 

Gender: M

**Data Entry Date**: 26/02/1999 **Weight (kg)**: 21

Hospitalisation: Age: 05Y

**Onset Date**: 28/10/1998 **DOB**:

Outcome: Causality: Causality probable

Recovered

**Information:** 90% recovered in 3-4 weeks with few residual lesions.

Reaction:

Preferred Term Severity Report Description Treatment

Urticaria Papular urticaria - pruritic

excoriated

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)**Reason: Behavior disorders of childhod

Tablet 10 Milligram Daily Oral

**Batch: Started:** 18/08/1998 **Stopped:** 18/11/1998

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Case Number: 137000

Gender: F

Data Entry Date: 08/03/1999 Weight (kg):

Hospitalisation: Age: 10Y

**Onset Date**: 31/12/1999 **DOB**:

Outcome: Causality: Causality possible

Recovered

Information: Drugs prescribed for attention deficit disorder with hyperactivity. reaction developed

after about 1 week of therapy. - the date of onset is not accurate but indicates that

onset occurred sometime during the year.

Reaction:

Preferred Term Severity Report Description Treatment

Tachycardia Tachycardia of 120 beats Zoloft discontinued

per minute

Medicine details:

CLONIDINE HYDROCHLORIDE (Suspected) Reason: Behavior disorders of childhod

0

Batch: Started: Stopped:

**DEXAMPHETAMINE SULPHATE (Suspected)**Reason: Behavior disorders of childhod

0

Batch: Started: Stopped:

**ZOLOFT (Suspected)** Reason: Behavior disorders of childhod

0

Batch: Started: Stopped: 10D

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**Case Number: 139469** 

Gender: M

Weight (kg):

**Data Entry Date**: 13/05/1999

Age: 4Y

**Hospitalisation:** 

. . . . . . . .

**Onset Date**: 04/05/1999 **DOB**:

Outcome: Causality: Causality possible

Recovered

Information: 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

Psychotic disorder Dexamphetamine and

clonertine ceased.

Medicine details:

CLONIDINE HYDROCHLORIDE (Suspected) Reason :

0

**Batch**: **Started**: 01/04/1999 **Stopped**: 04/05/1999 1M

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

Tablet 12.5 Milligram Daily Oral

**Batch**: **Started**: 01/04/1999 **Stopped**: 04/05/1999 1M

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**Case Number: 142046** 

Gender: F

**Data Entry Date: 29/07/1999** 

Weight (kg):

Hospitalisation: Admitted to hospital

**Age:** 35Y

Onset Date: 09/02/1999

DOB:

Outcome:

Causality: Causality probable

Recovered

Information: Dexamphetamine prescribed for add. the dosage start date is not necessarily accurate

but indicates that start occurred sometime during the month.

Reaction:

**Preferred Term** 

Delusion

Severity

**Report Description** 

**Treatment** 

Religious delusions Dexamphetamine ceased

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason:

Batch: Started: 01/01/1999 Stopped: 09/02/1999

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**Case Number: 142472** 

Gender: F

**Data Entry Date**: 09/08/1999

Weight (kg):

**Hospitalisation:** 

**Age:** 33Y

Onset Date: 05/08/1998

Outcome :

**DOB:** 19/08/1965

Recovered

Causality: Causality possible

Information:

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Rash erythematous

Rash on neck, chest, I. legs, painful, burning.

Betamethasone cream, paracetamol, codeine

phosphate, promethazine,

temazepam.

Medicine details:

**CARBAMAZEPINE (Suspected)** 

Reason: Other&unspecified epilepsy

Oral application

200 Milligram

5 Milligram

Daily

Oral

Batch : Started :

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason:

Oral

Oral application

Batch:

Started :

Daily

Stopped:

Stopped:

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**Case Number: 147610** 

Gender: F

**Data Entry Date**: 20/12/1999 **Weight (kg)**: 37

Hospitalisation: Age: 9Y

**Onset Date**: 10/09/1999 **DOB**:

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Purpura Bruise more on lower legs Dexamphetamine ceased.

less on arms.

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason:

2 Dose Unspec Daily

**Batch**: **Started**: 29/07/1999 **Stopped**: 23/09/1999

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**Case Number: 157650** 

Gender: M

**Data Entry Date**: 12/09/2000 **Weight (kg)**: 26

Hospitalisation: Age: 8Y

**Onset Date**: 01/08/2000 **DOB**: 16/05/1992

Outcome: Causality: Causality possible

Recovered

**Information:** Symptoms occurred 5 hours after the second dose of dexamphetamine therapy.

Reaction:

Preferred Term Severity Report Description Treatment

Face oedema Facial swelling.

Periorbital oedema Puffy eyes.

Dyspnoea Short of breath.

Abdominal pain Stomach cramps.

Bronchospasm Given hydrocortisone and

cessation of dexamphetamine.

Confusional state

Palpitations Tachycardia

#### Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason: Behavior disorders of childhod

15 Milligram Daily

**Batch: Started:** 01/08/2000 **Stopped:** 01/08/2000

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**Case Number: 157904** 

Gender: M

**Data Entry Date: 20/09/2000** 

Weight (kg):

**Hospitalisation:** 

Age: 32Y

Onset Date: 28/08/2000

**DOB:** 05/02/1968

Outcome:

Causality: Causality possible

Recovered

Severity

Information: Started efexor at 75mg daily and increased to 150mg daily after 7 days, used efexor 2-3 years previously with some anxiety and agitation occuring. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Reaction:

**Preferred Term** 

**Report Description** 

**Treatment** 

Muscle contractions

involuntary Agitation

Inducible ankle clonus

Ceased dexamphetamine and venlafaxine, cyproheptadine

given.

Anxiety

Chills

Convulsion

Hyperhidrosis

Hyperreflexia

Hypertonia

Tachycardia

Tremor

Medicine details:

**DEXAMPHETAMINE SULPHATE (Interaction)** 

Reason:

15 Milligram

Daily

Batch:

Started: 01/02/2000

Stopped:

CONTIN

**EFEXOR (Interaction)** 

Reason: Depression 150 Milligram

Daily

Batch:

Started: 20/08/2000

Stopped: 30/08/2000

Laboratory Investigations:

Type

Range

Date Tested Result

**Details** 

Electrocardiography

An ecg showed sinus tachycardia

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**Case Number: 157905** 

Gender: M

**Data Entry Date: 20/09/2000** 

Weight (kg):

Hospitalisation: Admitted to hospital

Age: 32Y

Onset Date: 28/08/2000

**DOB:** 05/02/1968

Outcome:

Causality: Causality possible

Recovered

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

sometime during the month.

Reaction:

**Preferred Term** 

Serotonin syndrome

Severity

**Report Description** 

**Treatment** 

Tachycardia Hypertonia

Hr was 140 beats/minute. Occasional muscle jerks.

Serotonergic syndrome.

Patient was hospitalised. date of recovery 30.8.00. treated with

periactin 8mg po.

Anxiety Chills

Hypertonia

Medicine details:

**CITALOPRAM HYDROBROMIDE (Interaction)** 

Reason:

Batch:

Started:

Stopped:

**DEXAMPHETAMINE SULPHATE (Interaction)** 

Reason:

Daily

Batch:

Started: 01/02/2000

Stopped:

CONTIN

**EFEXOR (Interaction)** 

Reason: Depression

0

150 Milligram

150 Milligram

15 Milligram

Daily

Daily

Batch:

Started: 20/08/2000

**Stopped**: 30/08/2000

THIORIDAZINE HYDROCHLORIDE (Interaction)

Reason:

Batch:

Started:

Stopped:

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**Case Number: 158958** 

Gender: M

**Data Entry Date:** 25/10/2000

Weight (kg):

**Hospitalisation:** 

Age: 6Y

Onset Date: 22/10/2000 DOB:

Outcome:

Causality: Causality possible

Recovered

Information: Patient also taking dexamphetamine. the dosage start date is not accurate but

indicates that start occurred sometime during the year.

Reaction:

Hyperkinesia

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Date of recovery 23/10/00.

Medicine details:

**BACOPA COMPLEX (Interaction)** 

Reason:

5 Millilitre

1 time

Batch:

Started:

Stopped:

**DEXAMPHETAMINE SULPHATE (Interaction)** 

Reason:

1 Dose Unspec Daily

Batch:

Started: 01/01/1997

Stopped:

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**Case Number: 161524** 

Gender: F

**Data Entry Date**: 13/02/2001 **Weight (kg)**: 53

Hospitalisation: Age: 33Y

**Onset Date**: 05/12/2000 **DOB**: 07/06/1967

Outcome: Causality: Causality possible

Recovered

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

sometime during the month.

Reaction:

Preferred Term Severity Report Description Treatment

Disturbance in attention Woke up in a daze. Date of recovery 6.12.00.

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)**Reason: Behavior disorders of childhod

20 Milligram Daily

Batch: Started: 01/02/2000 Stopped:

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**Case Number: 166984** 

Gender: M

**Data Entry Date**: 30/07/2001 **Weight (kg)**: 18

Hospitalisation: Age: 10Y

**Onset Date**: 02/05/2001 **DOB**: 01/03/1991

Outcome: Causality: Causality possible

Recovered

**Information:** Allergic to food colourings, dyes and preservatives.

Reaction:

Preferred Term Severity Report Description Treatment

Neurosis Babbling and singing+++.

Dystonia Dystonic reaction, jaw Date of recovery 3.5.01. treated

clenching. with benztropine orraly followed

by 0.4mg iv.

Hallucination Hyperkinesia

Medicine details:

CLONIDINE HYDROCHLORIDE (Suspected) Reason :

200 Microgram Daily

Batch: Started: Stopped: 02/05/2001

DEXAMPHETAMINE SULPHATE (Suspected) Reason:

2 Dose Unspec Daily

**Batch**: **Started**: 01/05/2001 **Stopped**: 02/05/2001

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**Case Number: 171379** 

Gender: M

**Data Entry Date: 20/12/2001** 

Onset Date: 28/02/2000

Weight (kg):

**Hospitalisation:** 

**Age:** 29Y

**DOB**: 04/05/1972

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Batch:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Renal pain

Pain in lower back

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason: Behavior disorders of childhod

Started: 01/01/1996

3 Dose Unspec Daily

**Stopped**: 28/12/2000

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**Case Number: 171721** 

Gender: M

**Data Entry Date**: 04/01/2002 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date: 28/03/2001 DOB: 02/07/1984

Outcome: Causality: Causality possible

Not yet recovered

Information: The date of onset is not necessarily accurate but indicates onset sometime in the

month. the dose start date for risperidone is not accurate but indicates the drug was

started sometime in the year.

Reaction:

Other data

Preferred Term Severity Report Description Treatment

Testicular disorder

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

Tablet 40 Milligram Daily Oral

Batch: Started: Stopped:

RISPERIDONE (Suspected) Reason :

3 Milligram Daily Oral

Batch: Started: 01/01/2000 Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

'pearl' lesion in his right testicle with

'pearl' lesion in his right testicle with small hydroceles. scrotal ultrasound 17.5.01 reveald palpable lump in right hemiscrotum, representing a calcified scrotal pearl, maximal diameter 7mm. scrotal ultrasound on 21.11.01

In march 01, he developed a bengin

demontrated small bilateral hydroceles

and right srotal pearl.

Other data Comparison with the previous

ultrasound of 17.5.01 indicates the size of the calcified right scrotal lesion is

unaltered.

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**Case Number: 176273** 

Gender: M

**Data Entry Date:** 18/06/2002

Weight (kg):

**Hospitalisation:** 

Age: 6Y

Onset Date: 30/04/2002

**DOB**: 10/11/1995

Outcome:

Causality: Causality possible

Not yet recovered

Information: The dose start date for luvox and dexamphetamine is not necessarily accurate b ut

indicates the drugs were started sometime in the month.

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Dyskinesia

Dyskinesia arms, mouth,

Required a doctor's visit.

tongue.

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason:

12.5 Milligram

12.5 Milligram

Daily

Batch:

Started: 01/01/2000

Stopped:

LUVOX (Suspected)

Reason:

Daily

Batch:

Started: 01/08/2001

Stopped: 09/05/2002

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**Case Number: 178109** 

Gender: F

**Data Entry Date**: 05/08/2002

Weight (kg):

**Hospitalisation:** 

Age: AD

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

male born 21/08/2001. birth defect - anorectal agenesis colonic

atresia horseshoe kidney and vesico-urethral reflex.

Reaction:

**Preferred Term** 

Neonatal disorder

Severity

**Report Description** 

**Treatment** 

Multiple congenital abnormalities

Anorecta/agenesis colonic atresia horseshoe kidney

Colostomy performed.

hospitalised.

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason:

Oral

....

15 Milligram

Daily

Stopped:

Tablet

Batch:

Started: 01/01/1995

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**Hospitalisation:** 

# **Public Case Detail**

**Case Number: 180113** 

Gender: F

**Data Entry Date**: 28/10/2002 **Weight (kg)**: 75

**Age:** 31Y

Onset Date: 01/09/2002

**DOB**: 27/01/1971

Outcome :

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dizziness Required a visit to doctor.

Orthostatic hypotension

Photophobia

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason: Behavior disorders of childhod

Tablet 30 Milligram Daily Oral

Batch: Started: 12/08/2002 Stopped:

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**Hospitalisation:** 

## **Public Case Detail**

**Case Number: 180876** 

Gender: F

**Data Entry Date**: 19/12/2002 **Weight (kg)**: 30

Age:

Onset Date: 20/11/2002 DOB: 29/10/1992

Outcome: 20/11/2002 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hallucination Hallucination and bad trip after Hypnovel with

confusion, muscle cramps, hyperventilation, seeing things lasted for 3 hrs

Confusional state Hyperventilation Muscle spasms

Medicine details:

**DEXAMPHETAMINE SULPHATE (Interaction)**Reason: Behavior disorders of childhod

5 Milligram Daily

Batch: Started: Stopped:

HYPNOVEL (Interaction) Reason :

20 Milligram Daily

Batch: Started: 20/11/2002 Stopped:

LIGNOCAINE (Interaction) Reason :

4 Millilitre Daily

Batch: Started: 20/11/2002 Stopped:

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**Case Number: 181998** 

Gender: M

**Data Entry Date:** 23/01/2003

Weight (kg): 0

Hospitalisation: Required a visit to the doctor

**Age:** 11Y

**Onset Date:** 

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Rash Required Visit to Doctor

Rash.

Dexamphetamine ceased.

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason: Behavior disorders of childhod Daily

Oral

Batch:

Started: 15/07/1999

10 Milligram

Stopped: 15/09/2002

PUSIME02 Page 40 of 65



Case Number: 191065

Gender: M

**Data Entry Date**: 02/10/2003 **Weight (kg)**: 0

**Hospitalisation:** Age: 25Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: Patient had history of alcohol abuse. On admission was diagnosed with first episode

psychosis. Improved within days of ceasing dexamphetamine and commencing

anti-psychotic medication

Reaction:

Preferred Term Severity Report Description Treatment

Depressed mood, suicidal

thoughts, insomnia, weight loss and delusions.

Delusion

Insomnia

Suicidal ideation

Weight decreased

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

Batch: Started: Stopped:

DOXEPIN HYDROCHLORIDE (Other drug) Reason :

50 Milligram Daily

Batch: Started: Stopped:

PUSIME02 Page 41 of 65



Gender: M

Case Number: 191066

**Data Entry Date**: 02/10/2003 **Weight (kg)**: 0

Hospitalisation: Age: 22Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: Treating team made diagnosis of disorganised schizophrenia. This patient failed to

improve on withdrawal of dexamphetamine and commencing anti-psychotic medication

Reaction:

Preferred Term Severity Report Description Treatment

Thinking abnormal Loosening of associations,

thought disorder and impaired judgement.

Judgement impaired

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

Dose Unspec

Batch: Started: Stopped:

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**Case Number : 191067** 

Gender: F

**Data Entry Date**: 02/10/2003 **Weight (kg)**: 0

Hospitalisation: Age: 18Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: Family history of bipolar disorder. Given diagnosis of dexamphetamine induced

psychosis. Improved within days of ceasing dexamphetamine and commencing anti

psychotic medication

Reaction:

Preferred Term Severity Report Description Treatment

Agitation Agitation, visual and auditory hallucinations,

incoherent speech and

disorientation.

Disorientation

Dysarthria

Hallucination, auditory

Hallucination, visual

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

50 Milligram Daily

Batch: Started: Stopped:

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Case Number: 191068

Hospitalisation: Age: 25Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: History of amphetamine abuse as teenager and had previous diagnosis of personality

disorder. She was diagnosed with brief psychotic episode (first admission) and drug

induced psychosis (second admission). Improved within days of ceasing

dexamphetamine and commencing anti-psychotic medication.

Reaction:

Preferred Term Severity Report Description Treatment

Aggression Verbal abuse, homicidal threats and auditory

hallucinations.

Hallucination, auditory Homicidal ideation

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

Dose Unspec

Batch: Started: Stopped:

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**Case Number : 191069** 

Gender: M

**Data Entry Date**: 02/10/2003 **Weight (kg)**: 0

Age: 41Y

Hospitalisation :

•

Onset Date : Outcome :

DOB:

Causality: Causality possible

Unknown

Information:

History of intravenous drug and cannabis abuse. On admission was diagnosed with

hypomania. Improved within days of ceasing dexamphetamine and commencing

anti-psychotic medication.

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Aggression

Aggressive behaviour, labile mood, irritability, delusions and agitation.

Agitation

Delusion

Irritability

Mood swings

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason:

40 Milligram

Daily

Batch :

Started:

Stopped:

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**Case Number : 191070** 

Gender: M

**Data Entry Date**: 02/10/2003 **Weight (kg)**: 0

Hospitalisation: Age: 37Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: Patient noted to have avoidant personality. Initially diagnosed with drug induced

psychosis. This was later changed to adjustment disorder. Improved within days of

ceasing dexamphetamine and commencing anti-psychotic medication

Reaction:

Preferred Term Severity Report Description Treatment

Neglect of personal

appearance

Self neglect, reduced volition, insomnia, poor concentration and suicidal

thoughts.

Apathy

Disturbance in attention

Insomnia

Suicidal ideation

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected)

Reason:

Dose Unspec

Batch : Started : Stopped :

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**Case Number: 192190** 

Gender: M

Data Entry Date: 13/11/2003

Weight (kg): 0

**Hospitalisation:** 

**Age:** 25Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity

**Report Description** 

**Treatment** 

Abnormal behaviour

Father reported "strange behaviour". Also felt that this product did not seem to have the same effect as

previous batches.

Drug effect decreased

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason:

**Tablet** 

Dose Unspec Oral

Batch: 35746

Started:

Stopped:

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**Case Number: 194796** 

Gender: M

**Data Entry Date**: 20/02/2004 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date : DOB : 20/05/1986

Outcome: Causality: Causality possible

Unknown

**Information:** The patient has a history of consistent oral muscular weakness and epileptic activity.

The weakness was more profound in the first one to one and a half hours in the

morning after taking Dexamphetamine.

The speech pathologist was concerned that this event may be due to a drug-drug

interaction between Catapres and Dexamphetamine.

Reaction:

Preferred Term Severity Report Description Treatment

Hypotonia

Hypotonia - increased, speech disorder - poor intelligibility in speech.

Speech disorder

Medicine details:

CATAPRES (Interaction) Reason :

Tablet 150 Microgram Daily Oral

Batch: Started: L TERM Stopped:

DEXAMPHETAMINE SULPHATE (Interaction) Reason :

10 Milligram Daily Oral

Batch: Started: Stopped:

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**Case Number: 198545** 

Gender: M

Data Entry Date: 28/06/2004 Weight (kg): 0

**Hospitalisation**: Treated in Accident/Emergency Depart Age:

Onset Date: 02/06/2004 DOB: 12/10/1991

Outcome: Causality: Causality possible

Not yet recovered

Information: Dosage had been increased from 18mg daily to 36mg daily and then to 40mg daily a

few days prior to onset of events.

Reaction:

Preferred Term Severity Report Description Treatment

Tachycardia Tachycardia and

palpitations.

**Palpitations** 

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

10 Milligram Daily

Batch: Started: L TERM Stopped: Continuing

Strattera (Suspected) Reason: Behavior disorders of childhod

Capsule 40 Milligram Daily Oral

Batch: Started: 03/05/2004 Stopped: Continuing

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Gender: M

**Case Number: 200199** 

**Data Entry Date**: 20/08/2004 **Weight (kg)**: 25

Hospitalisation: Age: 99U

Onset Date: 17/07/2004 DOB:

Outcome: 24/07/2004 Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Cheilitis Patient experienced Medication ceased after 3 days.

Dexamphetamine withdrawal, red lips the next day and then rash on trunk for several days

trunk for several days.

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

Batch: Started: Stopped:

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Case Number: 200788

Gender: M

**Data Entry Date**: 13/09/2004 **Weight (kg)**: 29

**Hospitalisation**: Admitted to hospital Age:

**Onset Date**: 24/07/2004 **DOB**: 10/08/1993

Outcome: 24/07/2004 Causality: Causality possible

Recovered

Information: Brother had similar episode 12 months earlier. Tourette's syndrome aslo diagnosed.

Reaction:

Preferred Term Severity Report Description Treatment

Dystonia Caused or prolonged Dystonic reaction, Benztropine 1mg IMI given.

inpatient peripheral hypertonia and hospitalisation decreased reflexes.

Hypertonia Caused or prolonged

inpatient hospitalisation

Hyporeflexia Caused or prolonged

inpatient hospitalisation

**Medicine details:** 

CLONIDINE HYDROCHLORIDE (Suspected) Reason :

250 Microgram Daily

Batch: Started: Stopped: 23/07/2004

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

Tablet 20 Milligram Daily Oral

Batch: Started: Stopped: 23/07/2004

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Case Number: 202887

Gender: U

**Data Entry Date:** 19/11/2004

Weight (kg): 22.6

Hospitalisation: Admitted to hospital

Age:

**Onset Date:** 

**DOB**: 30/07/1997

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

**Preferred Term** Severity **Report Description** 

**Treatment** 

Anxiety

Caused or prolonged inpatient

Patient developed significant anxiety and

hospitalisation

Obsessive-compulsive

Caused or prolonged

OCD symptoms.

disorder

inpatient

hospitalisation

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason: Behavior disorders of childhod

10 Milligram

10 Milligram

Daily

Stopped: 15/06/2004

**RITALIN (Suspected)** 

Batch:

Reason: Behavior disorders of childhod

Daily

Oral

Batch:

Started: 15/07/2004

Started: 15/04/2004

Stopped: 15/09/2004

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Case Number: 202891

Gender: U

**Data Entry Date:** 19/11/2004 Weight (kg): 22.6

Hospitalisation: Admitted to hospital Age:

**DOB**: 30/07/1997 **Onset Date:** 

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

**Preferred Term** Severity **Report Description Treatment** Luvox ceased.

Caused or prolonged Obsessive-compulsive The patient developed disorder inpatient obsessive compulsive

hospitalisation disorder.

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)** Reason: Behavior disorders of childhod

> 5 Milligram Daily

Batch: Started: Stopped:

LUVOX (Suspected) Reason: Behavior disorders of childhod

Tablet Oral

Batch: Started: Stopped: 0

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**Case Number : 203217** 

Gender: M

**Data Entry Date**: 01/12/2004

Weight (kg): 0

**Hospitalisation:** 

Age:

Onset Date: 15/05/2004

**DOB:** 15/08/1988

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Severity Report Description

**Treatment** 

Retinal pigmentation

Required Visit to

Macula: abnormal pigmentary granulation of

Investigated, no treatment.

Doctor

both maculae.

both ma

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason: Unspecified neurosis

Batch:

Started:

L TERM

Stopped:

**RITALIN (Suspected)** 

Reason: Unspecified neurosis

Oral

Batch :

Started:

LTERM

Stopped:

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**Case Number: 204541** 

Gender: F

**Data Entry Date**: 24/01/2005 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date : DOB : 22/06/1961

Outcome: Causality: Causality certain

Not yet recovered

Information: Symptoms disappeared when drug stopped for a few days but recurred when drug

restarted.

Reaction:

Preferred Term Severity Report Description Treatment

Fatigue The patient experienced odd symptoms - she was

tired and had blurred

vision.

Vision blurred

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

 $\textbf{Batch}: \hspace{1.5cm} \textbf{Started}: \hspace{1.5cm} 03/10/2004 \hspace{1.5cm} \textbf{Stopped}: \\$ 

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**Case Number : 205311** 

Onset Date: 15/01/2005

Gender: F

**Data Entry Date**: 16/02/2005 **Weight (kg)**: 0

Hospitalisation : Age :

Outcome : Causality : Causality possible

Unknown

Information: History includes explosive mood swings

Reaction:

Preferred Term Severity Report Description Treatment

Anger The child has experienced Ceased Dexamphetamine, increasing episodes of changed to Strattera.

anger and has made an attempt to leave home (run

**DOB**: 06/04/1997

away).

Abnormal behaviour

Mood swings

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason: Behavior disorders of childhod

Batch: Started: Stopped:

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**Case Number : 209092** 

Gender: F

**Data Entry Date**: 24/06/2005

Weight (kg): 60

**Hospitalisation**: Admitted to hospital

Age:

Onset Date: 18/05/2005

**DOB**: 23/05/1930

Outcome: 26/05/2005

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description

**Treatment** 

Hyponatraemia

Caused or prolonged inpatient

The patient developed

severe hyponatraemia with vomiting and weakness after 2 doses of Efexor XR.

Asthenia

Caused or prolonged

inpatient

hospitalisation

hospitalisation

Vomiting

Caused or prolonged

inpatient

hospitalisation

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected)

Reason: Behavior disorders of childhod

10 Milligram

Weekly

Batch :

Started :

Stopped :

**EFEXOR-XR** (Suspected)

Reason: Depression

Capsule

75 Milligram

Daily Oral

Batch:

**Started**: 16/05/2005

Stopped: 17/05/2005

**ACTONEL** (Other drug)

Reason: Osteoporosis

Batch :

Started :

 $\mathsf{L}\,\mathsf{TERM}$ 

L TERM

Stopped:

KLIOVANCE (Other drug)

Stopped:

Seretide 500/50 Accuhaler (Other drug)

Reason: Asthma

Batch:

Batch:

Started:

Started:

L TERM

Stopped:

SPIRIVA (Other drug)

Reason : Otr respiratory systm diseases

Reason: Menopausal symptoms

Batch :

Started :

L TERM

Stopped:

Laboratory Investigations:

Type Sodium Range

Date Tested Result

Details S. Na 123

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**Case Number: 210013** 

Gender: M

**Data Entry Date**: 21/07/2005 **Weight (kg)**: 76

**Hospitalisation**: Required a visit to the doctor Age:

**Onset Date**: 15/01/2003 **DOB**: 05/04/1958

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Tinnitus The patient developed tinnitus, dull hearing and

skin sores.

Hearing impaired

Skin ulcer

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)**Reason: Behavior disorders of childhod

20 Milligram Daily

**Batch**: **Started**: 15/11/2002 **Stopped**: 15/07/2003

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Case Number: 217074 Gender: F

**Data Entry Date**: 06/04/2006 **Weight (kg)**: 60

Hospitalisation: Age: 44Y

**Onset Date**: 15/12/2005 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Erythema Patient developed red

hands, she also developed yellow finger nails.

Stopped:

Nail discolouration

Batch:

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)**Reason: Cataplexy&narcolepsy brain dis

20 Milligram Daily

Batch: Started: 15/12/2005 Stopped:

LASIX (Other drug) Reason : Hered&famil nerv systm dis nos

40 Milligram

Batch: Started: Stopped:

OXYBUTYNIN HYDROCHLORIDE (Other drug) Reason : Hered&famil nerv systm dis nos

3 Dose Unspec

ZOTON (Other drug) Reason : Hered&famil nerv systm dis nos

1 Dose Unspec

Started:

Batch: Started: Stopped:

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**Hospitalisation:** 

## **Public Case Detail**

Case Number: 217094

Gender: M

**Data Entry Date**: 06/04/2006 **Weight (kg)**: 92

Age:

Onset Date: 21/03/2006

**DOB**: 26/07/1934

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Tremor Incapacity/disability Patient experienced

shaking epilepitic like shaking, itching skin, restlessness, cannot sleep, unable to walk without aid.

Abasia Incapacity/disability
Insomnia Incapacity/disability
Pruritus Incapacity/disability
Restlessness Incapacity/disability

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason:

2 Dose Unspec Daily Oral

**Batch**: **Started**: 21/03/2006 **Stopped**: 24/03/2006 0

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Case Number: 222988

Gender: F

**Data Entry Date**: 09/11/2006 **Weight (kg)**: 65

**Hospitalisation**: Required a visit to the doctor Age:

**Onset Date**: 25/09/2006 **DOB**: 21/01/1990

Outcome: 05/10/2006 Causality: Causality probable

Recovered

Information: Similar reaction with Zoloft and dexamphetamine.

Reaction:

Preferred Term Severity Report Description Treatment

Mydriasis Dilated pupils only occurred when dose

increased

Therapy regimen changed

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)**Reason: Behavior disorders of childhod

22.5 Milligram Daily

Batch: Started: Stopped:

LUVOX (Suspected) Reason : Depression

 Tablet
 50 Milligram
 Daily
 Oral

 Batch :
 Started : 11/09/2006
 Stopped : 05/10/2006

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**Hospitalisation:** 

## **Public Case Detail**

**Case Number: 232910** 

Gender: F

**Data Entry Date**: 03/09/2007 **Weight (kg)**: 55

Age:

**Onset Date**: 01/04/2007 **DOB**: 20/04/1949

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Cardiomyopathy Life threatening severe cardiomyopathy withdrawal of dexamphetamine.

while taking high doses of initiation of ACEI and beta

dexamphetamine blocker

Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason :

Tablet 12 Dose Unspec Daily Oral

**Batch**: **Started**: 01/01/2005 **Stopped**: 16/04/2007

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**Case Number: 234161** 

Gender: F

**Data Entry Date**: 10/10/2007 **Weight (kg)**: 78

**Hospitalisation**: Required a visit to the doctor **Age**: 17Y

**Onset Date**: 19/09/2007 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information: Patient started dexamphetamine 15/09 1 morning and 1 midmorning for 2 days, then 2

in the morning and 1 midmorning.

Reaction:

Preferred Term Severity Report Description Treatment

Aggression Dexamphetamine started 15/9/07. On Wed 19/9/07

experienced aggression, violent behaviour,

uncontrollable sobbing and

shakiness.

Aggression

Crying

Tremor

#### Medicine details:

DEXAMPHETAMINE SULPHATE (Suspected) Reason:

2 Dose Unspec Daily

**Batch**: **Started**: 15/09/2007 **Stopped**: 0

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Reaction:

# **Public Case Detail**

Case Number: 234228

Data Entry Date: 10/10/2007

Hospitalisation:

Gender: F

Weight (kg): 0

Age:

**Onset Date: DOB:** 04/12/1985

Outcome : Causality : Causality possible

Unknown

Information: Patient was not cortisol deficient. History of spondyloarthropathy and narcolepsy.

Preferred Term	Severity	Report Description	Treatment
Hypoglycaemia		Patient developed postprandial hypoglycaemia.	
Medicine details :			
AZATHIOPRINE (Suspected)		Reason :	
Batch :	Started :	Stopped :	
DEXAMPHETAMINE SULPHATE (Suspected)		Reason :	
Batch :	Started :	Stopped :	
Humira (Suspected)		Reason :	
Injection		1 Dose Unspec	
Batch :	Started :	Stopped :	0
VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason :	
Batch :	Started :	Stopped :	

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Case Number: 240461

Gender: F

**Data Entry Date: 29/04/2008** 

Weight (kg): 0

**Hospitalisation:** 

Age:

**Onset Date:** 

**DOB**: 22/05/1951

Outcome:

Causality: Causality certain

Unknown

Information: Cert/rechallenge.

Reaction:

**Preferred Term** 

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

Dry mouth

Patient developed severe xerostomia with distressing Dexamphetamine withdrawn.

Changed to Ritalin 60mg/daily.

burning of oral mucosa.

Burning sensation mucosal

Medicine details:

**DEXAMPHETAMINE SULPHATE (Suspected)** 

Reason:

1 Dose Unspec Daily

Oral

Batch:

**Tablet** 

Started: 14/03/2008

Stopped:

Lexapro (Other drug)

Reason:

Daily

Oral

Batch:

Started:

Stopped:

**ZOCOR (Other drug)** 

Reason:

Daily

Oral

Batch:

Tablet

Started:

Stopped:

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

10 Milligram

40 Milligram

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