

Cases Count: 68

Case Number: 26044

Gender: M

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

Hospitalisation: Age: 65Y

Onset Date: 15/06/1982 **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 Patient experienced Dexamphetamine discontinued.

dryness of mouth chewing action of teeth causing mouth tenderness.

Stomatitis

Medicine details:

Dexamphetamine Sulphate (Suspected) Reason : Obesity othr than endoc origin

30 Milligram Daily

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

PUTRAN02 Page 1 of 69



Cases Count: 68

Case Number: 38758

Gender: M

Data Entry Date: 20/06/1985

Onset Date: 12/10/1982

Weight (kg): 0

Hospitalisation:

Age: 10Y

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Muscle twitching Severity

Report Description

Treatment

Patient developed multiple

intermittent motor tics.

Medicine details:

Dexamphetamine Sulphate (Suspected)

Reason: Behavior disorders of childhood Daily

Oral

Batch:

Started: 29/07/1981

5 Milligram

Stopped:

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Cases Count: 68

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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Cases Count: 68

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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Cases Count: 68

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:

PUTRAN02 Page 5 of 69



Cases Count: 68

Case Number: 91885

Gender: M

Data Entry Date: 30/03/1994

Weight (kg): 20

Hospitalisation:

Age: 06Y

Onset Date: 17/03/1994

DOB:

Outcome:

Not yet recovered

Causality: Causality possible

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

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Cases Count: 68

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

Batch:

Medicine details:

Dexamphetamine Sulphate (Suspected)

Reason:

Daily

2.5 Milligram

Started: 24/09/1994

Stopped: 07/11/1994

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Cases Count: 68

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

Daily

Oral

Batch:

Started: 22/09/1994

Stopped: 27/10/1994

Dexamphetamine Sulphate (Suspected)

Reason:

Oral

Tablet

5 Milligram

Daily

Batch:

Started: 15/09/1994

Stopped:

Laboratory Investigations:

Range

Type Electroencephalograph Date Tested Result

Details

Eeg post seizure showed definite

epileptiform activity.

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Cases Count: 68

Case Number: 99607

Gender: M

Data Entry Date: 16/03/1995

Weight (kg): 75

DOB:

Hospitalisation:

0 (0)

Onset Date: 15/01/1995

Age: 14Y

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

PUTRAN02 Page 9 of 69



Cases Count: 68

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

Medicine details:

Dexamphetamine Sulphate (Interaction)

Reason:

Oral

Batch :

Tablet

Started: 01/01/1986

Daily

Stopped :

Minomycin (Interaction)

Reason: Other acne of sebaceous glands

0

15 Milligram

Batch :

Started: 01/01/1995

Stopped:

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Cases Count: 68

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 childhood

5 Milligram Daily

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

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Hospitalisation:

Public Case Detail

Cases Count: 68

Case Number: 112816

Gender: M

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

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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Cases Count: 68

Case Number: 113842

Gender: F

Data Entry Date: 13/12/1996

Weight (kg): 55 Age: 15Y

Hospitalisation:

Onset Date: 28/08/1996

DOB:

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Peripheral ischaemia Severity

Report Description

Treatment

Painful blue and cold

hands.

Medicine details:

Dexamphetamine Sulphate (Suspected)

Reason:

15 Milligram

Daily

Batch: Started:

Stopped: 28/08/1996

1 Dose Unspec Daily

Batch:

Started:

Stopped:

CONTIN

Naproxen (Other drug)

Logynon Ed (Other drug)

Reason: Other disturbance of sensation

Reason: Painful menstruation

500 Milligram Daily

Batch:

Started: 21/08/1996

Stopped:

CONTIN

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Cases Count: 68

Gender: M

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

Decreased appetite

Medicine details:

Dexamphetamine Sulphate (Suspected) Reason :

Tablet 0 Oral

Batch : Started : Stopped :

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Cases Count: 68

Case Number: 116910 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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Cases Count: 68

Case Number: 117240

Gender: F

Data Entry Date: 05/05/1997

Weight (kg): 47

DOB:

Hospitalisation:

Age: 12Y

Onset Date: 07/04/1997

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:

Oral

10 Milligram

Daily

Stopped: 08/04/1997

Tablet Batch:

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Cases Count: 68

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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Cases Count: 68

Case Number: 125344

Gender: ∪

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 hour and dexamphetamine recommenced.

Reaction:

Preferred Term

Severity Report Description

Treatment

Hyperkinesia

Agitation

Zoloft and dexamphetamine

ceased.

Nervousness

Medicine details:

Dexamphetamine Sulphate (Suspected)

Reason: Behavior disorders of childhood

Oral application

Oral

Oral

Batch :

Started :

0

Stopped :

Zoloft (Suspected)

Reason: Behavior disorders of childhood

Tablet

25 Milligram Daily

Hyperstimulation

Batch :

Started :

Stopped:

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Cases Count: 68

Case Number: 125348

Gender: U

Data Entry Date: 26/02/1998

Weight (kg):

Hospitalisation: Admitted to hospital

Age: AC

DOB:

Onset Date:

Outcome:

Causality: Causality possible

Recovered

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

Reaction:

Preferred Term

Severity

Treatment

Hyperkinesia

Hyperstimulation

Report Description

Zoloft and dexamphetamine

ceased

Nervousness

Agitation

Medicine details:

Dexamphetamine Sulphate (Suspected)

Reason: Alcoholism

Oral application

0

Oral

Batch:

Started:

Stopped:

Zoloft (Suspected)

Reason: Alcoholism 25 Milligram

Daily

Oral

Batch:

Tablet

Started:

Stopped:

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Cases Count: 68

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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Cases Count: 68

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 childhood

3 Dose Unspec Daily

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

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Cases Count: 68

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 childhood

Tablet 10 Milligram Daily Oral

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

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Cases Count: 68

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 per minute

Zoloft discontinued

Medicine detai	ls:			
Clonidine Hydrochloride (Suspected)			Reason: Behavior disorders of childhood	
	C)		
Batch :	Started :		Stopped :	
Dexamphetamine Sulphate (Suspected)			Reason: Behavior disorders of childhood	
	C)		
Batch :	Started :		Stopped :	
Zoloft (Suspected)			Reason: Behavior disorders of childhood	
	C)		
Batch :	Started :		Stopped :	10D

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Cases Count: 68

Gender: M

Case Number: 139469

Data Entry Date: 13/05/1999 Weight (kg):

Hospitalisation: Age: 4Y

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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Cases Count: 68

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.

Reason:

Reaction:

Preferred Term

Delusion

Severity

Report Description

Treatment

Religious delusions

Dexamphetamine ceased

Medicine details:

Dexamphetamine Sulphate (Suspected)

Batch:

Started: 01/01/1999

Stopped: 09/02/1999

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Cases Count: 68

Case Number: 142472

Gender: F

Data Entry Date: 09/08/1999

Weight (kg):

Hospitalisation:

Age: 33Y

Onset Date: 05/08/1998

DOB: 19/08/1965

Outcome:

Causality: Causality possible

Recovered

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: **Dexamphetamine Sulphate (Suspected)**

Reason:

Daily

Oral

Oral application Batch:

Started:

Started:

Stopped:

Stopped:

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Cases Count: 68

Case Number: 147610

Gender: F

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

Hospitalisation: Age: 9Y

Onset Date: 10/09/1999 DOB:

Causality: Causality probable Outcome:

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

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

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Cases Count: 68

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 childhood

15 Milligram Daily

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

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Cases Count: 68

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

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

Severity

Report Description Inducible ankle clonus **Treatment**

Muscle contractions

involuntary

Agitation

Ceased dexamphetamine and

venlafaxine, cyproheptadine

given.

Anxiety

Chills

Convulsion

Hyperhidrosis

Hyperreflexia

Hypertonia

Tachycardia

Tremor

Medicine details:

Dexamphetamine Sulphate (Interaction)

Reason:

Daily

15 Milligram

Started: 01/02/2000 Batch:

Stopped:

CONTIN

Efexor (Interaction)

Batch:

Reason: Depression

Daily 150 Milligram

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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Cases Count: 68

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 Severity **Report Description Treatment**

Tachycardia Hr was 140 beats/minute. Hypertonia Occasional muscle jerks.

Serotonin syndrome Serotonergic syndrome. Patient was hospitalised. date of

recovery 30.8.00. treated with

periactin 8mg po.

Anxiety Chills

Medicine details:

Citalopram Hydrobromide (Interaction) Reason:

0

Batch: Started: Stopped:

Dexamphetamine Sulphate (Interaction) Reason:

15 Milligram

Daily

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

Efexor (Interaction) Reason: Depression

> 150 Milligram Daily

Batch: Started: 20/08/2000 Stopped: 30/08/2000

Thioridazine Hydrochloride (Interaction) Reason:

> 150 Milligram Daily

Batch: Stopped: Started:

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Cases Count: 68

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:

Preferred Term Severity Report Description Treatment

Hyperkinesia 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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Cases Count: 68

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 childhood

20 Milligram Daily

Batch: Started: 01/02/2000 Stopped:

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Cases Count: 68

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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Cases Count: 68

Case Number: 171379

Gender: M

Data Entry Date: 20/12/2001

Weight (kg):

Hospitalisation:

Age: 29Y

Onset Date: 28/02/2000

DOB: 04/05/1972

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Report Description

Treatment

Severity Pain in lower back Renal pain

Medicine details:

Dexamphetamine Sulphate (Suspected)

Reason: Behavior disorders of childhood

3 Dose Unspec Daily

Batch:

Started: 01/01/1996

Stopped: 28/12/2000

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Cases Count: 68

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:

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

Other data In march 01, he developed a bengin

'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

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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Cases Count: 68

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

Daily

Batch:

Started: 01/01/2000

Stopped:

Luvox (Suspected)

Reason:

12.5 Milligram

Daily

Batch:

Started: 01/08/2001

Stopped: 09/05/2002

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Cases Count: 68

Case Number: 178109

Gender: M

Data Entry Date: 05/08/2002

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Mother took

Treatment Colostomy.

Neonatal disorder

Caused or prolonged inpatient

Dexamphetamine for ADHD til 20/40 gestation.

hospitalisation

Birth defect - anorectal agenesis, colonic atresia, horseshoe kidney and

vesico-urethral reflux.

Multiple congenital abnormalities

Medicine details:

Dexamphetamine Sulphate (Suspected)

Reason:

15 Milligram

Oral

Batch:

Started: 01/01/1995

Daily

Stopped:

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Cases Count: 68

Case Number: 180113

Gender: F

Data Entry Date: 28/10/2002

Weight (kg): 75

Hospitalisation:

Age: 31Y

Onset Date: 01/09/2002

DOB: 27/01/1971

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Dizziness

Severity

Report Description

Treatment

Required a visit to doctor.

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Orthostatic hypotension

Photophobia

Medicine details:

Dexamphetamine Sulphate (Suspected)

Reason: Behavior disorders of childhood

Tablet Batch:

30 Milligram

Started: 12/08/2002

Daily

Stopped:

Oral

PUTRAN02



Hospitalisation:

Public Case Detail

Cases Count: 68

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 childhood

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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Cases Count: 68

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 childhood Daily

Oral

Batch:

Started: 15/07/1999

10 Milligram

Stopped: 15/09/2002

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Cases Count: 68

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:

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Cases Count: 68

Case Number : 191066

Gender: M

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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Cases Count: 68

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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Cases Count: 68

Case Number: 191068

Gender: F

Weight (kg): 0

Data Entry Date: 02/10/2003

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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Cases Count: 68

Case Number: 191069

Gender: M

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

Hospitalisation: Age: 41Y

Onset Date : DOB :

Outcome: 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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Cases Count: 68

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 Self neglect, reduced appearance 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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Cases Count: 68

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

to have the same effect a previous batches.

Drug effect decreased

Medicine details:

Dexamphetamine Sulphate (Suspected)

Reason:

Tablet

Dose Unspec Oral

Batch: 35746

Started:

Stopped:

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Cases Count: 68

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:

PUTRAN02 Page 48 of 69



Cases Count: 68

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 childhood

Capsule 40 Milligram Daily Oral

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

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Cases Count: 68

Medication ceased after 3 days.

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
Dexamphetamine
withdrawal, red lips the
next day and then rash on

trunk for several days.

Rash

Medicine details:

Dexamphetamine Sulphate (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 68

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 decreased reflexes. hospitalisation

Caused or prolonged Hypertonia

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: Stopped: 23/07/2004 Started:

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Cases Count: 68

Case Number: 202887

Gender: U

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

Age:

Hospitalisation: Admitted to hospital

DOB: 30/07/1997

Outcome:

Causality: Causality possible

Unknown

Information:

Onset Date:

Reaction:

Preferred Term Severity **Report Description Treatment**

Anxiety Caused or prolonged Patient developed

inpatient

significant anxiety and hospitalisation OCD symptoms.

Caused or prolonged Obsessive-compulsive

disorder

inpatient hospitalisation

Medicine details:

Dexamphetamine Sulphate (Suspected) Reason: Behavior disorders of childhood

> 10 Milligram Daily

Started: 15/04/2004 Batch: Stopped: 15/06/2004

Ritalin (Suspected) Reason: Behavior disorders of childhood

> 10 Milligram Daily

Batch: Started: 15/07/2004 Stopped: 15/09/2004

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Cases Count: 68

Case Number: 202891

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

Obsessive-compulsive

Caused or prolonged

The patient developed obsessive compulsive

Luvox ceased.

disorder

inpatient hospitalisation

disorder.

Medicine details:

Dexamphetamine Sulphate (Suspected)

Reason: Behavior disorders of childhood

5 Milligram

Daily

Batch :

Started:

Stopped :

Luvox (Suspected)

Reason: Behavior disorders of childhood

Oral

Batch:

Tablet

Started :

Stopped :

0

PUTRAN02

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Cases Count: 68

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.

Medicine details:

Dexamphetamine Sulphate (Suspected)

Reason: Unspecified neurosis

Batch:

Started:

L TERM

Stopped:

Ritalin (Suspected)

Reason: Unspecified neurosis

Oral

Batch:

Started:

L TERM

Stopped:

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Cases Count: 68

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 :

Batch: Started: 03/10/2004 Stopped:

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Cases Count: 68

Case Number: 205311

Gender: F

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

Onset Date: 15/01/2005 **DOB**: 06/04/1997

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

away).

Abnormal behaviour

Mood swings

Medicine details:

Dexamphetamine Sulphate (Suspected) Reason: Behavior disorders of childhood

Batch: Started: Stopped:

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Cases Count: 68

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

jea in

The patient developed severe hyponatraemia with

inpatient hospitalisation

vomiting and weakness after 2 doses of Efexor XR.

Asthenia Caused or prolonged

inpatient

hospitalisation

Vomiting Caused or prolonged

inpatient

hospitalisation

Medicine details :

Reason: Behavior disorders of childhood

10 Milligram

Weekly

Batch :

Started :

Stopped :

Efexor-XR (Suspected)

Dexamphetamine Sulphate (Suspected)

Reason: Depression

Daily

Capsule

75 Milligram

ily Oral

Batch :

Started: 16/05/2005

Stopped: 17/05/2005

Actonel (Other drug)

Reason: Osteoporosis

Batch :

Started:

L TERM

Stopped :

Kliovance (Other drug)

Reason: Menopausal symptoms

Batch :

Started:

Started:

L TERM

Stopped:

Seretide 500/50 Accuhaler (Other drug)

Reason : Asthma

Stopped :

Spiriva (Other drug)

Batch:

L TERM

Reason : Otr respiratory systm diseases

Batch :

Sodium

Started :

Stopped:

Laboratory Investigations:

Type Range

Date Tested Result

L TERM

Details

S. Na 123

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Cases Count: 68

Case Number: 210013

Gender: M

Data Entry Date: 21/07/2005

Weight (kg): 76

Hospitalisation: Required a visit to the doctor

Age:

DOB: 05/04/1958

Outcome:

Onset Date: 15/01/2003

Not yet recovered

Causality: Causality possible

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 childhood

20 Milligram

Daily

Batch:

Started: 15/11/2002

Stopped: 15/07/2003

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Cases Count: 68

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

Erythema

Severity

Report Description Treatment

Patient developed red

hands, she also developed yellow finger nails.

Nail discolouration

Medicine details:

Dexamphetamine Sulphate (Suspected)

Reason: Cataplexy&narcolepsy brain dis

20 Milligram

Daily

Batch:

Started: 15/12/2005

Reason : Hered&famil nerv systm dis nos

Lasix (Other drug)

40 Milligram

Batch :

Started:

Stopped:

Stopped:

Oxybutynin Hydrochloride (Other drug)

Reason: Hered&famil nerv systm dis nos

3 Dose Unspec

Batch:

Started:

Stopped :

Zoton (Other drug)

Reason: Hered&famil nerv systm dis nos

1 Dose Unspec

Batch :

Started:

Stopped:

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Hospitalisation:

Public Case Detail

Cases Count: 68

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)

2 Dose Unspec Daily Oral

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

Reason:

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Cases Count: 68

Case Number: 222988

Gender: F

Age:

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

Hospitalisation: Required a visit to the doctor

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 childhood

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

Cases Count: 68

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:

Cardiomyopathy

Preferred Term Severity **Report Description Treatment**

> 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

Life threatening

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

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Cases Count: 68

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.

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

Cases Count: 68

Case Number: 234228 Gender: F

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

Hospitalisation : 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 Hypoglycaemia	Severity	Report Description Patient developed postprandial hypoglycaemia.	Treatment
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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Cases Count: 68

Case Number: 240461

Gender: F

Age:

Data Entry Date: 29/04/2008 Weight (kg): 0

Hospitalisation:

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 Dexamphetamine withdrawn. xerostomia with distressing

burning of oral mucosa.

Changed to Ritalin 60mg/daily.

Burning sensation mucosal

Medicine details:

Dexamphetamine Sulphate (Suspected) Reason:

Tablet 1 Dose Unspec Daily Oral

Batch: Started: 14/03/2008 Stopped:

Lexapro (Other drug) Reason:

> 10 Milligram Daily Oral

Batch: Started: Stopped:

Zocor (Other drug) Reason:

Tablet 40 Milligram Daily Oral

Batch: Started: Stopped:

PUTRAN02 Page 65 of 69



Cases Count: 68

Case Number : 245436

Gender: M

Data Entry Date: 14/10/2008

Weight (kg): 0

Hospitalisation:

Age: 17Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information: Possibility if the original diagnosis was wrong.

Reaction:

Sexual abuse

Preferred Term Severity Report Description Treatment

history of abnormal behaviour was on Ritalin for ADHD from unknown date for two years. Previous to receiving Ritalin, the patient was prescribed the stimulant dexamphetamine from the age of 7 years untill 12 years. The patient was jailed for three years for attempted sexual assault. He had been drinking, and used the drug "ice" for the first time before he attempted the sexual assault. It was reported that there was a possibility if the original diagnosis was wrong, then it was likely that his intellectual and psychological development had been severely

Teenage patient with

affected.

Alcohol abuse Drug abuse

Medicine details:

Dexamphetamine Sulphate (Suspected) Reason :

Batch: Started: Stopped:

Ritalin (Suspected) Reason : Behavior disorders of childhood

Tablet 1 Dose Unspec Daily Oral

Batch: Started: Stopped:

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Cases Count: 68

Case Number: 253498

Gender: M

Data Entry Date: 12/07/2009

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age:

Onset Date: 28/09/2008

DOB: 30/04/1984

Outcome: 18/10/2008

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment Patient found by friends

Loss of consciousness Life threatening

> lying on the floor unconscious with twitching movements. He was

diaphoretic, had bilateral nystagmus, dilated pupils, myoclonic jerks, rigidity, hyperreflexia and clonus.

He was intubated for airway protection. A midazolam infusion was commenced and ICU admission was arranged. he was continued on high dose

benzodiazepines.

Clonus Life threatening Hyperhidrosis Life threatening Hyperreflexia Life threatening Muscle rigidity Life threatening Muscle twitching Life threatening Mydriasis Life threatening Myoclonus Life threatening

Medicine details:

Nystagmus

Alcohol (Suspected) Reason :

Started: 27/09/2008 Batch: Stopped: 28/09/2008

Dexamphetamine Sulphate (Suspected) Reason:

Tablet 1 Dose Unspec 1 time Oral

Life threatening

Started: 27/09/2008 Stopped: 27/09/2008 Batch:

Ecstasy (m.d.m.a.) (Suspected) Reason:

Tablet 1 Dose Unspec 1 time Oral

Batch: Started: 27/09/2008 Stopped: 27/09/2008

Lithium Carbonate (Suspected) Reason: Depression

> 750 Milligram Daily

Batch: Started: L TERM **Stopped:** 28/09/2008

Phenelzine Sulphate (Suspected) Reason: Depression

> 45 Milligram Daily

Batch: Started: L TERM Stopped: 28/09/2008

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Quetiapine (Suspected) Reason : Depression

500 Milligram Daily

Batch: Started: L TERM Stopped: 28/09/2008

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Cases Count: 68

Case Number: 255388

Gender: M

Data Entry Date: 14/08/2009 **Weight (kg)**: 0

Hospitalisation: Age: 23Y

Onset Date : DOB :

Outcome: Causality: Causality probable

Recovered

Information: Ceased Champix and problems resolved almost immediately.

Reaction:

Preferred Term Severity Report Description Treatment

Paradoxical drug reaction Patient reported effects of

dexamphetamine

dramatically reduced since started Champix. Said it was like he wasn't taking it. Reported marked difficulty

in concentrating, forgetfullness and drowsiness.

Medicine details:

Champix (Interaction) Reason :

Tablet 1 Dose Unspec Daily Oral

Batch: **Started**: 07/08/2009 **Stopped**: 0

Dexamphetamine Sulphate (Interaction) Reason :

Batch: Started: Stopped: 0

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

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