



**Australian Government**

**Department of Health**

Therapeutic Goods Administration

# Database of Adverse Event Notifications - medicines

## Medicine summary

You searched for the following **2 medicines** between **01/01/2008 – 19/08/2015**:

- Champix (Varenicline)
- Not specified (Varenicline)

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## Important information

The TGA uses adverse event reports to identify when a safety issue may be present. An adverse event report does not mean that the medicine is the cause of the adverse event. If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. The TGA strongly advises people taking prescription medicines not to change their medication regime without prior consultation with a health professional.

## About the Database of Adverse Event Notifications (DAEN) - medicines

- The DAEN - medicines contains information from reports of adverse events that the TGA has received in relation to medicines including vaccines used in Australia.
- The DAEN - medicines does not contain all known safety information about a particular medicine. Please do not make an assessment about the safety of a medicine based on the information in the DAEN - medicines.

## The TGA medicine safety monitoring program

More information about the DAEN - medicines and the TGA medicines safety monitoring program is available at:

- About the DAEN - medicines <<http://www.tga.gov.au/safety/daen-about.htm>>
- Medicines safety <<http://www.tga.gov.au/safety/information-medicines.htm>>

You are encouraged to report an adverse event suspected of being related to a medicine used in Australia. Reports of adverse events in relation to medicines and vaccines can be reported using the 'blue card' reporting form, by phone and online <<http://www.tga.gov.au/safety/problem.htm>>.

## Other useful sources of information on Australian medicines

More information about a medicine is available from the Product Information (PI) <<http://www.tga.gov.au/hp/information-medicines-pi.htm>> and Consumer Medicine Information (CMI) <<http://www.tga.gov.au/consumers/information-medicines-cmi.htm>> leaflet or the labelling of the medicine. Australian Public Assessment Report for Prescription Medicines (AusPARs) <<http://www.tga.gov.au/industry/pm-auspar.htm>> for some prescription medicines, are also available from the TGA website. <<http://www.tga.gov.au>>  
Your health professional can also provide help and assistance on how to use medicines.  
Information on medicines used in Australia is available from NPS MedicineWise <<http://www.nps.org.au/>>.

## About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of the adverse events reported to the TGA, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

Copyright restrictions apply to the DAEN - medicines <<http://www.tga.gov.au/about/website-copyright.htm>>.

## Results

Number of reports (cases): 1951

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 1852

(The TGA thinks there is a possibility that the medicine caused the adverse event)

Number of cases where death was a reported outcome: 38

(These reports of death may or may not have been a result of taking a medicine)

MedDRA system organ class <sup>i</sup>	MedDRA reaction term <sup>ii</sup>	Number of cases <sup>iii</sup>	Number of cases with a single suspected medicine <sup>iv</sup>	Number of cases where death was a reported outcome <sup>v</sup>
Psychiatric disorders	Completed suicide	32	32	31
Cardiac disorders	Myocardial infarction	17	16	3
Psychiatric disorders	Suicidal ideation	241	229	2
Psychiatric disorders	Aggression	131	122	2
Psychiatric disorders	Depression	414	404	1
Psychiatric disorders	Insomnia	160	156	1
Psychiatric disorders	Nightmare	75	71	1
Psychiatric disorders	Mood swings	70	69	1
Psychiatric disorders	Psychotic disorder	69	66	1
Psychiatric disorders	Abnormal behaviour	67	62	1
General disorders and administration site conditions	Feeling abnormal	62	58	1
Psychiatric disorders	Paranoia	50	50	1
Psychiatric disorders	Suicide attempt	43	39	1
Gastrointestinal disorders	Constipation	25	25	1
Gastrointestinal disorders	Abdominal pain upper	25	23	1
Nervous system disorders	Loss of consciousness	12	9	1
Psychiatric disorders	Homicidal ideation	12	12	1
Cardiac disorders	Acute myocardial infarction	10	8	1
Injury, poisoning and procedural complications	Overdose	7	5	1
Blood and lymphatic system disorders	Thrombocytopenia	4	2	1
Investigations	Liver function test abnormal	4	3	1
Skin and subcutaneous tissue disorders	Purpura	1	1	1
Renal and urinary disorders	Renal failure	1	1	1
Gastrointestinal disorders	Nausea	254	244	0
Psychiatric disorders	Anxiety	133	127	0

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Psychiatric disorders	Agitation	132	124	0
Psychiatric disorders	Depressed mood	105	103	0
Psychiatric disorders	Abnormal dreams	96	93	0
Nervous system disorders	Headache	96	94	0
Gastrointestinal disorders	Vomiting	87	79	0
Psychiatric disorders	Hallucination	80	74	0
Nervous system disorders	Dizziness	74	69	0
Psychiatric disorders	Anger	71	69	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea	61	59	0
Psychiatric disorders	Irritability	51	49	0
General disorders and administration site conditions	Fatigue	50	49	0
General disorders and administration site conditions	Malaise	46	44	0
Psychiatric disorders	Mood altered	43	39	0
Nervous system disorders	Tremor	41	38	0
Psychiatric disorders	Confusional state	38	35	0
General disorders and administration site conditions	Chest pain	38	35	0
Skin and subcutaneous tissue disorders	Rash	37	36	0
Nervous system disorders	Disturbance in attention	33	30	0
Nervous system disorders	Amnesia	33	24	0
Nervous system disorders	Memory impairment	33	30	0
Nervous system disorders	Seizure	32	28	0
Cardiac disorders	Palpitations	32	31	0
Psychiatric disorders	Thinking abnormal	32	32	0
Skin and subcutaneous tissue disorders	Pruritus	30	29	0
Psychiatric disorders	Panic attack	29	27	0
Nervous system disorders	Dysgeusia	29	29	0
General disorders and administration site conditions	Condition aggravated	29	27	0
Gastrointestinal disorders	Diarrhoea	28	25	0
Psychiatric disorders	Sleep disorder	28	27	0
Nervous system disorders	Somnolence	27	24	0
General disorders and administration site conditions	Crying	27	26	0

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Metabolism and nutrition disorders	Decreased appetite	27	27	0
Gastrointestinal disorders	Abdominal distension	26	25	0
Psychiatric disorders	Personality change	23	23	0
Psychiatric disorders	Withdrawal syndrome	22	21	0
Gastrointestinal disorders	Dry mouth	22	22	0
Gastrointestinal disorders	Abdominal pain	21	18	0
Eye disorders	Vision blurred	21	20	0
Nervous system disorders	Paraesthesia	20	20	0
Psychiatric disorders	Emotional disorder	20	20	0
Nervous system disorders	Lethargy	20	18	0
Skin and subcutaneous tissue disorders	Hyperhidrosis	20	18	0
Vascular disorders	Hypertension	19	19	0
Psychiatric disorders	Mania	19	19	0
Psychiatric disorders	Suicidal behaviour	19	19	0
Skin and subcutaneous tissue disorders	Urticaria	18	17	0
Investigations	Weight increased	17	17	0
Nervous system disorders	Hypoaesthesia	16	16	0
Psychiatric disorders	Disorientation	16	14	0
General disorders and administration site conditions	Chest discomfort	15	14	0
Gastrointestinal disorders	Dyspepsia	15	15	0
Gastrointestinal disorders	Haematochezia	15	13	0
Eye disorders	Visual impairment	15	14	0
General disorders and administration site conditions	Pain	15	15	0
Psychiatric disorders	Social avoidant behaviour	15	15	0
Psychiatric disorders	Mental disorder	15	14	0
Psychiatric disorders	Self-injurious ideation	14	14	0
General disorders and administration site conditions	Drug ineffective	14	14	0
Nervous system disorders	Dysarthria	13	11	0
Psychiatric disorders	Tearfulness	13	12	0
Gastrointestinal disorders	Mouth ulceration	13	12	0
Nervous system disorders	Migraine	13	13	0
Musculoskeletal and connective tissue disorders	Myalgia	12	11	0

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Musculoskeletal and connective tissue disorders	Muscle spasms	12	12	0
Psychiatric disorders	Restlessness	12	12	0
Nervous system disorders	Syncope	12	12	0
Psychiatric disorders	Affect lability	12	11	0
Gastrointestinal disorders	Flatulence	12	11	0
Investigations	Heart rate increased	12	11	0
Musculoskeletal and connective tissue disorders	Arthralgia	12	12	0
Immune system disorders	Hypersensitivity	11	10	0
Metabolism and nutrition disorders	Increased appetite	11	11	0
General disorders and administration site conditions	Gait disturbance	11	10	0
Psychiatric disorders	Fear	11	11	0
Cardiac disorders	Tachycardia	11	11	0
Gastrointestinal disorders	Swollen tongue	11	9	0
Injury, poisoning and procedural complications	Road traffic accident	11	8	0
General disorders and administration site conditions	Pyrexia	11	9	0
Skin and subcutaneous tissue disorders	Swelling face	10	10	0
Psychiatric disorders	Stress	10	10	0
Nervous system disorders	Speech disorder	10	9	0
Psychiatric disorders	Hallucination, auditory	10	9	0
General disorders and administration site conditions	Asthenia	10	10	0
Musculoskeletal and connective tissue disorders	Back pain	10	10	0
Skin and subcutaneous tissue disorders	Blister	10	9	0
Investigations	Blood glucose increased	10	10	0
Gastrointestinal disorders	Abdominal discomfort	10	10	0
Psychiatric disorders	Delusion	10	10	0
General disorders and administration site conditions	Drug interaction	9	1	0
Nervous system disorders	Ageusia	9	8	0
Psychiatric disorders	Apathy	9	8	0
Investigations	Blood pressure increased	9	9	0
Psychiatric disorders	Hallucination, visual	9	9	0

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Gastrointestinal disorders	Haematemesis	9	8	0
Respiratory, thoracic and mediastinal disorders	Dysphonia	8	7	0
Gastrointestinal disorders	Lip swelling	8	7	0
General disorders and administration site conditions	Drug withdrawal syndrome	8	8	0
Skin and subcutaneous tissue disorders	Cold sweat	8	8	0
Nervous system disorders	Coordination abnormal	8	6	0
Nervous system disorders	Cerebrovascular accident	8	8	0
Ear and labyrinth disorders	Vertigo	8	8	0
Psychiatric disorders	Violence-related symptom	8	8	0
Nervous system disorders	Balance disorder	8	8	0
Skin and subcutaneous tissue disorders	Rash erythematous	8	8	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	8	8	0
Psychiatric disorders	Frustration	7	7	0
Skin and subcutaneous tissue disorders	Rash pruritic	7	7	0
Renal and urinary disorders	Pollakiuria	7	7	0
Psychiatric disorders	Nervousness	7	7	0
Musculoskeletal and connective tissue disorders	Pain in extremity	7	7	0
Nervous system disorders	Cognitive disorder	7	7	0
Psychiatric disorders	Negative thoughts	7	6	0
Vascular disorders	Hot flush	7	7	0
General disorders and administration site conditions	Chills	7	6	0
Psychiatric disorders	Dissociation	7	7	0
Injury, poisoning and procedural complications	Intentional overdose	7	6	0
Nervous system disorders	Hypersomnia	7	7	0
Injury, poisoning and procedural complications	Fall	7	6	0
General disorders and administration site conditions	Feeling hot	7	7	0
Psychiatric disorders	Flat affect	6	6	0
Vascular disorders	Hypotension	6	6	0
Psychiatric disorders	Intentional self-injury	6	6	0

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Psychiatric disorders	Libido decreased	6	6	0
Gastrointestinal disorders	Paraesthesia oral	6	6	0
Psychiatric disorders	Emotional distress	6	5	0
Injury, poisoning and procedural complications	Contusion	6	6	0
Social circumstances	Activities of daily living impaired	6	6	0
Investigations	Weight decreased	6	6	0
Infections and infestations	Pneumonia	6	6	0
General disorders and administration site conditions	Oedema peripheral	6	5	0
Psychiatric disorders	Personality disorder	6	5	0
Musculoskeletal and connective tissue disorders	Muscular weakness	6	6	0
Skin and subcutaneous tissue disorders	Rash generalised	6	5	0
Psychiatric disorders	Somnambulism	6	6	0
Nervous system disorders	Poor quality sleep	6	6	0
Psychiatric disorders	Psychiatric symptom	6	6	0
Psychiatric disorders	Self injurious behaviour	6	5	0
General disorders and administration site conditions	Feeling of body temperature change	5	5	0
Psychiatric disorders	Schizophrenia	5	5	0
Skin and subcutaneous tissue disorders	Rash maculo-papular	5	5	0
Nervous system disorders	Psychomotor hyperactivity	5	5	0
General disorders and administration site conditions	Swelling	5	5	0
Social circumstances	Impaired driving ability	5	5	0
Psychiatric disorders	Bipolar disorder	5	5	0
Gastrointestinal disorders	Hypoaesthesia oral	5	5	0
Psychiatric disorders	Hypomania	5	4	0
Metabolism and nutrition disorders	Hyponatraemia	5	2	0
Investigations	Heart rate irregular	5	5	0
Respiratory, thoracic and mediastinal disorders	Haemoptysis	5	5	0
Nervous system disorders	Generalised tonic-clonic seizure	5	5	0
Respiratory, thoracic and mediastinal disorders	Epistaxis	5	5	0
Respiratory, thoracic and mediastinal disorders	Cough	5	5	0



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Psychiatric disorders	Depression suicidal	5	5	0
Cardiac disorders	Arrhythmia	5	4	0
Nervous system disorders	Ataxia	5	5	0
Skin and subcutaneous tissue disorders	Acne	5	5	0
Psychiatric disorders	Affective disorder	4	4	0
Skin and subcutaneous tissue disorders	Alopecia	4	4	0
Reproductive system and breast disorders	Breast pain	4	4	0
Nervous system disorders	Depressed level of consciousness	4	4	0
Nervous system disorders	Coma	4	3	0
General disorders and administration site conditions	Feeling drunk	4	3	0
Nervous system disorders	Epilepsy	4	4	0
Nervous system disorders	Dyskinesia	4	3	0
Gastrointestinal disorders	Gingival bleeding	4	4	0
Gastrointestinal disorders	Gastroesophageal reflux disease	4	4	0
Ear and labyrinth disorders	Hyperacusis	4	4	0
Nervous system disorders	Incoherent	4	3	0
General disorders and administration site conditions	Influenza like illness	4	4	0
Psychiatric disorders	Logorrhoea	4	4	0
Reproductive system and breast disorders	Menorrhagia	4	3	0
Nervous system disorders	Mental impairment	4	4	0
Nervous system disorders	Restless legs syndrome	4	4	0
Psychiatric disorders	Major depression	4	4	0
Psychiatric disorders	Bradyphrenia	4	4	0
General disorders and administration site conditions	Peripheral swelling	4	3	0
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	4	4	0
Ear and labyrinth disorders	Tinnitus	4	4	0
General disorders and administration site conditions	Therapeutic response unexpected	4	4	0
Nervous system disorders	Visual field defect	4	4	0
Respiratory, thoracic and mediastinal disorders	Wheezing	4	4	0
Renal and urinary disorders	Urinary incontinence	4	3	0

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Nervous system disorders	Presyncope	4	3	0
Eye disorders	Photophobia	4	4	0
Skin and subcutaneous tissue disorders	Skin exfoliation	4	3	0
Renal and urinary disorders	Renal pain	4	4	0
Skin and subcutaneous tissue disorders	Night sweats	4	4	0
Vascular disorders	Pallor	4	4	0
Gastrointestinal disorders	Pancreatitis	3	2	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal oedema	3	1	0
Musculoskeletal and connective tissue disorders	Muscle twitching	3	2	0
Renal and urinary disorders	Micturition urgency	3	3	0
Musculoskeletal and connective tissue disorders	Neck pain	3	2	0
Gastrointestinal disorders	Retching	3	3	0
Gastrointestinal disorders	Salivary hypersecretion	3	3	0
Eye disorders	Photopsia	3	3	0
Metabolism and nutrition disorders	Polydipsia	3	2	0
Infections and infestations	Viral infection	3	3	0
Social circumstances	Bedridden	3	3	0
Nervous system disorders	Transient ischaemic attack	3	3	0
General disorders and administration site conditions	Thirst	3	3	0
Investigations	Blood glucose fluctuation	3	3	0
Social circumstances	Verbal abuse	3	3	0
Skin and subcutaneous tissue disorders	Pruritus generalised	3	3	0
Musculoskeletal and connective tissue disorders	Joint swelling	3	3	0
Metabolism and nutrition disorders	Hyperglycaemia	3	3	0
Metabolism and nutrition disorders	Hypoglycaemia	3	3	0
General disorders and administration site conditions	Hunger	3	3	0
Respiratory, thoracic and mediastinal disorders	Hyperventilation	3	3	0
Renal and urinary disorders	Haematuria	3	3	0
Nervous system disorders	Formication	3	3	0
Psychiatric disorders	Feeling of despair	3	3	0

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Metabolism and nutrition disorders	Fluid retention	3	3	0
Vascular disorders	Flushing	3	2	0
Gastrointestinal disorders	Dysphagia	3	3	0
General disorders and administration site conditions	Feeling cold	3	2	0
Psychiatric disorders	Euphoric mood	3	3	0
Eye disorders	Eye pain	3	3	0
Nervous system disorders	Burning sensation	3	1	0
Metabolism and nutrition disorders	Diabetes mellitus	3	3	0
Eye disorders	Dry eye	3	3	0
Eye disorders	Blindness	3	3	0
Cardiac disorders	Atrial fibrillation	3	3	0
Nervous system disorders	Anosmia	3	3	0
Renal and urinary disorders	Acute kidney injury	3	3	0
Psychiatric disorders	Terminal insomnia	2	2	0
Infections and infestations	Candida infection	2	2	0
General disorders and administration site conditions	Inflammation	2	2	0
Reproductive system and breast disorders	Erectile dysfunction	2	2	0
General disorders and administration site conditions	Drug intolerance	2	2	0
Psychiatric disorders	Antisocial behaviour	2	2	0
Nervous system disorders	Aphasia	2	2	0
Immune system disorders	Anaphylactic reaction	2	2	0
Psychiatric disorders	Agoraphobia	2	2	0
Nervous system disorders	Akathisia	2	2	0
Investigations	Alanine aminotransferase increased	2	2	0
Psychiatric disorders	Acute psychosis	2	2	0
Cardiac disorders	Atrial flutter	2	2	0
Psychiatric disorders	Anhedonia	2	2	0
Musculoskeletal and connective tissue disorders	Arthritis	2	2	0
Psychiatric disorders	Bipolar I disorder	2	2	0
Respiratory, thoracic and mediastinal disorders	Asthma	2	2	0
Eye disorders	Blepharospasm	2	2	0

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Investigations	Blood creatine phosphokinase increased	2	2	0
Reproductive system and breast disorders	Breast tenderness	2	2	0
Psychiatric disorders	Bruxism	2	2	0
Cardiac disorders	Bundle branch block left	2	2	0
Reproductive system and breast disorders	Breast enlargement	2	2	0
General disorders and administration site conditions	Discomfort	2	2	0
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	2	2	0
Psychiatric disorders	Depersonalisation	2	2	0
Skin and subcutaneous tissue disorders	Dermatitis	2	2	0
Psychiatric disorders	Delusional perception	2	2	0
Metabolism and nutrition disorders	Dehydration	2	1	0
Psychiatric disorders	Delirium	2	2	0
Cardiac disorders	Cardiac failure	2	2	0
Psychiatric disorders	Conversion disorder	2	2	0
General disorders and administration site conditions	Concomitant disease aggravated	2	2	0
Investigations	Blood pressure decreased	2	2	0
Eye disorders	Eye swelling	2	2	0
Eye disorders	Eyelid oedema	2	2	0
Gastrointestinal disorders	Eructation	2	2	0
Skin and subcutaneous tissue disorders	Erythema	2	1	0
Respiratory, thoracic and mediastinal disorders	Dry throat	2	2	0
Renal and urinary disorders	Enuresis	2	2	0
Nervous system disorders	Dystonia	2	2	0
Renal and urinary disorders	Dysuria	2	2	0
General disorders and administration site conditions	Feeling jittery	2	2	0
Psychiatric disorders	Flashback	2	2	0
Investigations	Gamma-glutamyltransferase increased	2	2	0
Psychiatric disorders	Hallucinations, mixed	2	2	0

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General disorders and administration site conditions	Hangover	2	1	0
Nervous system disorders	Head discomfort	2	2	0
Gastrointestinal disorders	Gastritis	2	2	0
Infections and infestations	Gingivitis	2	2	0
Psychiatric disorders	Initial insomnia	2	2	0
Injury, poisoning and procedural complications	Injury	2	2	0
Infections and infestations	Infection	2	2	0
Nervous system disorders	Judgement impaired	2	2	0
Reproductive system and breast disorders	Metrorrhagia	2	2	0
Social circumstances	Legal problem	2	2	0
Psychiatric disorders	Loss of libido	2	2	0
Infections and infestations	Lower respiratory tract infection	2	2	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	2	1	0
Blood and lymphatic system disorders	Lymphadenopathy	2	2	0
Metabolism and nutrition disorders	Food craving	2	2	0
Gastrointestinal disorders	Intestinal haemorrhage	2	2	0
Vascular disorders	Haemorrhage	2	2	0
Psychiatric disorders	Nicotine dependence	2	2	0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	2	2	0
Social circumstances	Impaired work ability	2	2	0
Social circumstances	Treatment noncompliance	2	2	0
Nervous system disorders	VIIIth nerve paralysis	2	2	0
Psychiatric disorders	Tension	2	2	0
Gastrointestinal disorders	Toothache	2	2	0
Social circumstances	Stress at work	2	2	0
General disorders and administration site conditions	Energy increased	2	2	0
Social circumstances	Alcohol use	2	0	0
Psychiatric disorders	Mental status changes	2	1	0
Eye disorders	Vitreous floaters	2	2	0
Psychiatric disorders	Psychotic behaviour	2	2	0
Renal and urinary disorders	Polyuria	2	2	0

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Psychiatric disorders	Post-traumatic stress disorder	2	2	0
Skin and subcutaneous tissue disorders	Psoriasis	2	2	0
Gastrointestinal disorders	Rectal haemorrhage	2	2	0
Skin and subcutaneous tissue disorders	Rash macular	2	2	0
Nervous system disorders	Sedation	2	2	0
Skin and subcutaneous tissue disorders	Skin discolouration	2	2	0
Skin and subcutaneous tissue disorders	Skin lesion	2	2	0
Skin and subcutaneous tissue disorders	Skin reaction	2	2	0
Psychiatric disorders	Sleep talking	2	2	0
Psychiatric disorders	Sleep terror	2	2	0
Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	2	2	0
Renal and urinary disorders	Nephrolithiasis	2	2	0
Infections and infestations	Nasopharyngitis	2	2	0
Eye disorders	Myopia	2	2	0
Nervous system disorders	Neuropathy peripheral	2	2	0
Psychiatric disorders	Middle insomnia	2	2	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	2	2	0
Cardiac disorders	Pericardial effusion	2	1	0
Eye disorders	Periorbital oedema	2	2	0
Psychiatric disorders	Panic reaction	2	2	0
Eye disorders	Ocular hyperaemia	2	1	0
General disorders and administration site conditions	Oedema	2	2	0
Infections and infestations	Oral candidiasis	2	2	0
Vascular disorders	Orthostatic hypotension	2	2	0
Musculoskeletal and connective tissue disorders	Osteoarthritis	1	1	0
Gastrointestinal disorders	Oral mucosal blistering	1	1	0
Gastrointestinal disorders	Oral pain	1	1	0
Gastrointestinal disorders	Oedema mouth	1	0	0
Gastrointestinal disorders	Oesophageal stenosis	1	1	0
Reproductive system and breast disorders	Oligomenorrhoea	1	1	0

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Musculoskeletal and connective tissue disorders	Pain in jaw	1	1	0
Respiratory, thoracic and mediastinal disorders	Painful respiration	1	1	0
Nervous system disorders	Paralysis	1	1	0
Nervous system disorders	Paresis	1	1	0
Nervous system disorders	Parosmia	1	1	0
Musculoskeletal and connective tissue disorders	Periarthritis	1	1	0
Psychiatric disorders	Perseveration	1	1	0
Psychiatric disorders	Phobia	1	1	0
Skin and subcutaneous tissue disorders	Petechiae	1	1	0
Nervous system disorders	Petit mal epilepsy	1	1	0
Eye disorders	Mydriasis	1	0	0
Nervous system disorders	Myoclonus	1	1	0
Nervous system disorders	Monoplegia	1	1	0
Nervous system disorders	Movement disorder	1	1	0
Nervous system disorders	Multiple sclerosis	1	1	0
Gastrointestinal disorders	Mouth haemorrhage	1	1	0
Psychiatric disorders	Neurosis	1	1	0
Blood and lymphatic system disorders	Neutropenia	1	0	0
Blood and lymphatic system disorders	Neutrophilia	1	1	0
Renal and urinary disorders	Nocturia	1	1	0
Psychiatric disorders	Obsessive thoughts	1	1	0
Psychiatric disorders	Obsessive-compulsive disorder	1	1	0
Skin and subcutaneous tissue disorders	Nail disorder	1	1	0
Nervous system disorders	Nervous system disorder	1	1	0
Infections and infestations	Rhinitis	1	1	0
Nervous system disorders	Retrograde amnesia	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	1	0	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract irritation	1	1	0
Nervous system disorders	Sensory loss	1	1	0
Nervous system disorders	Serotonin syndrome	1	1	0

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Investigations	Serum ferritin increased	1	1	0
Reproductive system and breast disorders	Sexual dysfunction	1	1	0
Cardiac disorders	Sinus bradycardia	1	1	0
Nervous system disorders	Sinus headache	1	1	0
Infections and infestations	Sinusitis	1	1	0
General disorders and administration site conditions	Sluggishness	1	1	0
Skin and subcutaneous tissue disorders	Skin disorder	1	1	0
Skin and subcutaneous tissue disorders	Skin fissures	1	1	0
Infections and infestations	Skin infection	1	1	0
Nervous system disorders	Quadriplegia	1	1	0
Respiratory, thoracic and mediastinal disorders	Rales	1	1	0
Renal and urinary disorders	Renal disorder	1	1	0
Skin and subcutaneous tissue disorders	Rash vesicular	1	1	0
Skin and subcutaneous tissue disorders	Rash papular	1	1	0
Reproductive system and breast disorders	Premenstrual syndrome	1	1	0
Psychiatric disorders	Pressure of speech	1	1	0
Social circumstances	Physical abuse	1	1	0
Social circumstances	Physical assault	1	1	0
Skin and subcutaneous tissue disorders	Piloerection	1	1	0
Skin and subcutaneous tissue disorders	Pityriasis rubra pilaris	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	1	0	0
Respiratory, thoracic and mediastinal disorders	Pulmonary thrombosis	1	1	0
Reproductive system and breast disorders	Polymenorrhoea	1	1	0
Respiratory, thoracic and mediastinal disorders	Productive cough	1	1	0
Investigations	Prostatic specific antigen increased	1	1	0
Eye disorders	Visual acuity reduced	1	1	0
Ear and labyrinth disorders	Vertigo labyrinthine	1	1	0



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Renal and urinary disorders	Urinary retention	1	1	0
Pregnancy, puerperium and perinatal conditions	Unintended pregnancy	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	1	1	0
Reproductive system and breast disorders	Vaginal discharge	1	1	0
Vascular disorders	Vasculitis	1	1	0
Cardiac disorders	Ventricular tachycardia	1	1	0
Renal and urinary disorders	Tubulointerstitial nephritis	1	0	0
Musculoskeletal and connective tissue disorders	Mobility decreased	1	1	0
Nervous system disorders	Multiple sclerosis relapse	1	1	0
Injury, poisoning and procedural complications	Wound secretion	1	1	0
General disorders and administration site conditions	Paradoxical drug reaction	1	0	0
Skin and subcutaneous tissue disorders	Yellow skin	1	1	0
Infections and infestations	Vulvovaginal candidiasis	1	1	0
Nervous system disorders	Subarachnoid haemorrhage	1	1	0
Injury, poisoning and procedural complications	Spinal fracture	1	1	0
Gastrointestinal disorders	Steatorrhoea	1	1	0
Pregnancy, puerperium and perinatal conditions	Stillbirth	1	1	0
Gastrointestinal disorders	Stomatitis	1	1	0
Cardiac disorders	Supraventricular tachycardia	1	1	0
Psychiatric disorders	Suspiciousness	1	1	0
Congenital, familial and genetic disorders	Tourette's disorder	1	1	0
Nervous system disorders	Transient global amnesia	1	1	0
Gastrointestinal disorders	Tongue ulceration	1	1	0
Nervous system disorders	Tonic convulsion	1	1	0
Vascular disorders	Thrombosis	1	1	0
Social circumstances	Theft	1	1	0
Nervous system disorders	Temporal lobe epilepsy	1	1	0
General disorders and administration site conditions	Tenderness	1	1	0
Psychiatric disorders	Thought blocking	1	1	0

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Respiratory, thoracic and mediastinal disorders	Throat irritation	1	1	0
Respiratory, thoracic and mediastinal disorders	Throat tightness	1	1	0
Gastrointestinal disorders	Anal inflammation	1	1	0
Musculoskeletal and connective tissue disorders	Muscle fatigue	1	1	0
Gastrointestinal disorders	Tongue dry	1	1	0
Injury, poisoning and procedural complications	Excoriation	1	0	0
Cardiac disorders	Tachyarrhythmia	1	1	0
General disorders and administration site conditions	Abasia	1	1	0
Respiratory, thoracic and mediastinal disorders	Nocturnal dyspnoea	1	1	0
Gastrointestinal disorders	Lip haemorrhage	1	1	0
General disorders and administration site conditions	Localised oedema	1	1	0
Nervous system disorders	Carotid artery occlusion	1	1	0
Gastrointestinal disorders	Chapped lips	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal discomfort	1	1	0
Vascular disorders	Deep vein thrombosis	1	1	0
Eye disorders	Altered visual depth perception	1	1	0
Injury, poisoning and procedural complications	Off label use	1	0	0
Psychiatric disorders	Depressive symptom	1	1	0
Skin and subcutaneous tissue disorders	Skin tightness	1	1	0
Respiratory, thoracic and mediastinal disorders	Rhinalgia	1	1	0
Psychiatric disorders	Laziness	1	1	0
Ear and labyrinth disorders	Ear discomfort	1	1	0
Psychiatric disorders	Thought broadcasting	1	1	0
Gastrointestinal disorders	Reflux gastritis	1	1	0
Gastrointestinal disorders	Gastrointestinal oedema	1	0	0
Infections and infestations	Staphylococcal infection	1	1	0
Vascular disorders	Aortic occlusion	1	1	0
Nervous system disorders	Dysgraphia	1	1	0
Metabolism and nutrition disorders	Fluid intake reduced	1	1	0

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Gastrointestinal disorders	Faecaloma	1	1	0
Skin and subcutaneous tissue disorders	Eczema weeping	1	1	0
Psychiatric disorders	Regressive behaviour	1	1	0
Skin and subcutaneous tissue disorders	Skin burning sensation	1	1	0
Psychiatric disorders	Dysphemia	1	1	0
Investigations	Blood alkaline phosphatase increased	1	1	0
Investigations	Blood alcohol increased	1	0	0
Investigations	Hepatic enzyme increased	1	1	0
Psychiatric disorders	Disturbance in social behaviour	1	1	0
Eye disorders	Eye movement disorder	1	1	0
Injury, poisoning and procedural complications	Pelvic fracture	1	1	0
Gastrointestinal disorders	Gastric disorder	1	1	0
Psychiatric disorders	Daydreaming	1	1	0
Nervous system disorders	Cerebral vasoconstriction	1	1	0
Renal and urinary disorders	Micturition disorder	1	1	0
Reproductive system and breast disorders	Menstruation delayed	1	1	0
Injury, poisoning and procedural complications	Medication error	1	1	0
General disorders and administration site conditions	Loss of control of legs	1	1	0
Social circumstances	Loss of employment	1	0	0
Infections and infestations	Kidney infection	1	1	0
Injury, poisoning and procedural complications	Laceration	1	0	0
Psychiatric disorders	Lack of spontaneous speech	1	0	0
Eye disorders	Lacrimation increased	1	1	0
Psychiatric disorders	Limited symptom panic attack	1	1	0
Gastrointestinal disorders	Lip oedema	1	1	0
Gastrointestinal disorders	Intestinal obstruction	1	1	0
Gastrointestinal disorders	Irritable bowel syndrome	1	1	0
Hepatobiliary disorders	Jaundice	1	0	0
Injury, poisoning and procedural complications	Joint dislocation	1	1	0
Nervous system disorders	Hyporeflexia	1	0	0

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Metabolism and nutrition disorders	Hypokalaemia	1	1	0
Nervous system disorders	Hypokinesia	1	1	0
General disorders and administration site conditions	Impaired healing	1	1	0
Psychiatric disorders	Impulsive behaviour	1	1	0
Psychiatric disorders	Inappropriate affect	1	1	0
Psychiatric disorders	Hypnopompic hallucination	1	1	0
Endocrine disorders	Hyperthyroidism	1	1	0
Metabolism and nutrition disorders	Hyperphagia	1	1	0
Nervous system disorders	Hyperaesthesia	1	1	0
Gastrointestinal disorders	Hyperchlorhydria	1	1	0
Nervous system disorders	Hemiparesis	1	1	0
Hepatobiliary disorders	Hepatic function abnormal	1	1	0
Hepatobiliary disorders	Hepatitis	1	0	0
Gastrointestinal disorders	Glossitis	1	1	0
Gastrointestinal disorders	Glossodynia	1	1	0
Congenital, familial and genetic disorders	Glucose-6-phosphate dehydrogenase deficiency	1	1	0
Metabolism and nutrition disorders	Gout	1	1	0
Gastrointestinal disorders	Gastritis erosive	1	1	0
Gastrointestinal disorders	Gingival pain	1	1	0
Investigations	Blood urine present	1	1	0
Gastrointestinal disorders	Gastric haemorrhage	1	1	0
Gastrointestinal disorders	Gastric ulcer	1	1	0
Infections and infestations	Furuncle	1	1	0
Psychiatric disorders	Feelings of worthlessness	1	1	0
General disorders and administration site conditions	Food interaction	1	1	0
Ear and labyrinth disorders	Ear pain	1	1	0
Skin and subcutaneous tissue disorders	Ecchymosis	1	1	0
Investigations	Electrocardiogram abnormal	1	1	0
Psychiatric disorders	Elevated mood	1	1	0
Skin and subcutaneous tissue disorders	Dry skin	1	1	0
General disorders and administration site conditions	Face oedema	1	1	0

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General disorders and administration site conditions	Facial pain	1	1	0
Gastrointestinal disorders	Faeces discoloured	1	1	0
Social circumstances	Excessive exercise	1	1	0
Nervous system disorders	Extrapyramidal disorder	1	0	0
Cardiac disorders	Extrasystoles	1	1	0
Eye disorders	Eye disorder	1	1	0
Infections and infestations	Eye infection	1	1	0
Eye disorders	Eye irritation	1	1	0
Social circumstances	Child abuse	1	1	0
Congenital, familial and genetic disorders	Colour blindness	1	1	0
Musculoskeletal and connective tissue disorders	Costochondritis	1	1	0
Social circumstances	Contraindication to medical treatment	1	1	0
Eye disorders	Cataract subcapsular	1	1	0
Psychiatric disorders	Catatonia	1	1	0
Nervous system disorders	Cerebral infarction	1	1	0
Investigations	C-reactive protein increased	1	1	0
Cardiac disorders	Cardiac arrest	1	1	0
Gastrointestinal disorders	Cheilitis	1	1	0
Respiratory, thoracic and mediastinal disorders	Choking	1	1	0
Respiratory, thoracic and mediastinal disorders	Choking sensation	1	1	0
Musculoskeletal and connective tissue disorders	Chondrocalcinosis pyrophosphate	1	1	0
Eye disorders	Chromatopsia	1	1	0
Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	1	1	0
Psychiatric disorders	Claustrophobia	1	1	0
Blood and lymphatic system disorders	Coagulopathy	1	1	0
Gastrointestinal disorders	Coeliac disease	1	1	0
Psychiatric disorders	Dependence	1	1	0
Infections and infestations	Cystitis	1	1	0
Ear and labyrinth disorders	Deafness	1	1	0
General disorders and administration site conditions	Decreased activity	1	1	0

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Psychiatric disorders	Decreased interest	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis bullous	1	0	0
Psychiatric disorders	Derealisation	1	1	0
Psychiatric disorders	Disinhibition	1	0	0
Metabolism and nutrition disorders	Diabetes mellitus inadequate control	1	1	0
Nervous system disorders	Dreamy state	1	0	0
Psychiatric disorders	Drug abuse	1	0	0
General disorders and administration site conditions	Drug effect decreased	1	0	0
Skin and subcutaneous tissue disorders	Drug eruption	1	1	0
Reproductive system and breast disorders	Breast induration	1	1	0
Investigations	Blood potassium decreased	1	1	0
Respiratory, thoracic and mediastinal disorders	Bronchospasm	1	1	0
Eye disorders	Blindness transient	1	1	0
Investigations	Blood zinc decreased	1	1	0
Musculoskeletal and connective tissue disorders	Bone pain	1	1	0
Nervous system disorders	Brain hypoxia	1	1	0
Reproductive system and breast disorders	Breast engorgement	1	1	0
Renal and urinary disorders	Bladder pain	1	1	0
Investigations	Biopsy skin abnormal	1	1	0
Eye disorders	Asthenopia	1	1	0
Investigations	Aspartate aminotransferase increased	1	1	0
Cardiac disorders	Atrioventricular block	1	1	0
Psychiatric disorders	Agitated depression	1	0	0
Gastrointestinal disorders	Abdominal pain lower	1	1	0
Gastrointestinal disorders	Abdominal tenderness	1	1	0
Infections and infestations	Abscess oral	1	1	0
Injury, poisoning and procedural complications	Accidental overdose	1	0	0
Investigations	Acid base balance abnormal	1	1	0

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Psychiatric disorders	Alcohol abuse	1	0	0
Metabolism and nutrition disorders	Alcohol intolerance	1	0	0
Injury, poisoning and procedural complications	Alcohol poisoning	1	0	0
Nervous system disorders	Altered state of consciousness	1	0	0
Reproductive system and breast disorders	Amenorrhoea	1	1	0
Blood and lymphatic system disorders	Anaemia	1	0	0
Immune system disorders	Anaphylactic shock	1	1	0
Cardiac disorders	Angina pectoris	1	1	0
Skin and subcutaneous tissue disorders	Angioedema	1	1	0
Injury, poisoning and procedural complications	Lower limb fracture	1	1	0
Psychiatric disorders	Abnormal sleep-related event	1	0	0
Psychiatric disorders	Somatic hallucination	1	1	0
Respiratory, thoracic and mediastinal disorders	Increased upper airway secretion	1	1	0
Renal and urinary disorders	Renal impairment	1	0	0
Infections and infestations	Respiratory tract infection	1	1	0
Musculoskeletal and connective tissue disorders	Limb discomfort	1	1	0
Ear and labyrinth disorders	Sudden hearing loss	1	1	0
Gastrointestinal disorders	Gastrointestinal ulcer	1	1	0
Injury, poisoning and procedural complications	Drug dose omission	1	1	0
Injury, poisoning and procedural complications	Drug administration error	1	1	0
Injury, poisoning and procedural complications	Incorrect dose administered	1	1	0
Injury, poisoning and procedural complications	Extra dose administered	1	1	0
Injury, poisoning and procedural complications	Circumstance or information capable of leading to medication error	1	1	0
General disorders and administration site conditions	Breakthrough pain	1	0	0
Eye disorders	Dark circles under eyes	1	1	0
Psychiatric disorders	Tachyphrenia	1	1	0
Psychiatric disorders	Hypersexuality	1	1	0

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Gastrointestinal disorders	Stomach mass	1	1	0
Infections and infestations	Post procedural infection	1	1	0
General disorders and administration site conditions	Apparent death	1	1	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal blistering	1	1	0
Nervous system disorders	Brain injury	1	1	0
Skin and subcutaneous tissue disorders	Butterfly rash	1	1	0
General disorders and administration site conditions	Inhibitory drug interaction	1	0	0
Gastrointestinal disorders	Mouth swelling	1	1	0
Injury, poisoning and procedural complications	Intentional product use issue	1	1	0
General disorders and administration site conditions	Product commingling	1	1	0
Psychiatric disorders	Executive dysfunction	1	1	0
Injury, poisoning and procedural complications	Toxicity to various agents	1	0	0
Psychiatric disorders	Substance-induced psychotic disorder	1	1	0
Eye disorders	Lid sulcus deepened	1	1	0
Social circumstances	Partner stress	1	1	0
Nervous system disorders	Anosognosia	1	0	0

## Footnotes

<sup>i</sup> A description of what, in general terms, was affected by the adverse event, as described by the Medical Dictionary for Regulatory Activities MedDRA (for example 'cardiac disorders')

<sup>ii</sup> A description of the adverse event as defined by MedDRA; these adverse events are grouped by system organ class. You can use the MedlinePlus medical dictionary <<http://www.nlm.nih.gov/medlineplus/mplusdictionary.html>> to look up terms.

<sup>iii</sup> The number of cases for which each type of adverse event was reported

<sup>iv</sup> Results show where a medicine is the only medicine suspected to be related to the adverse event

<sup>v</sup> These reports of death may or may not have been the result of taking a medicine