

Chlorpromazine hydrochloride to end January 2009

Case Count			Case Group	Death Outcomes	Sole	
			569	17	234	
Medicine	Reaction Count	Blood and lymphatic system disorders	Anaemia	3	0	0
			Aplastic anaemia	3	1	0
			Pancytopenia	3	1	2
			Thrombocythaemia	1	0	0
			Thrombocytopenia	6	1	1
			Lymphadenopathy	3	1	1
			Eosinophilia	5	0	0
			Leukocytosis	5	0	1
			Leukopenia	9	0	2
			Lymphopenia	2	0	1
			Agranulocytosis	14	3	3
			Febrile neutropenia	1	0	1
			Neutropenia	20	2	3
			Blood and lymphatic system disorders	75	9	15
		Cardiac disorders	Bradycardia	1	0	0
			Extrasystoles	3	0	0
			Tachycardia	19	0	7
			Sinus tachycardia	1	0	0
			Cardiac arrest	1	0	0
			Cardiac disorder	1	0	0
			Cyanosis	2	0	0
			Palpitations	3	0	1
			Left ventricular failure	1	0	0
			Cardiomyopathy	1	0	0
			Cardiomegaly	1	0	0
			Ventricular dysfunction	1	0	0
			Ventricular hypertrophy	1	0	0
			Myocarditis	4	0	0
			Cardiac disorders	40	0	8
		Congenital, familial and genetic disorders	Congenital foot malformation	1	0	0
			Congenital, familial and genetic disorders	1	0	0
		Ear and labyrinth disorders	Ototoxicity	1	0	0
			Deafness	3	0	0
			Tinnitus	1	0	0
			Ear and labyrinth disorders	5	0	0
		Endocrine disorders	Cushing's syndrome	1	0	0
			Inappropriate antidiuretic hormone secretion	1	0	0
			Hyperthyroidism	1	0	1
			Hypothyroidism	1	0	0
			Endocrine disorders	4	0	1

Chlorpromazine hydrochloride to end January 2009

			Case Group	Death Outcomes	Sole		
Medicine	Reaction Count	Eye disorders	Cataract	3	0	0	
			Cataract subcapsular	2	0	0	
			Eye disorder	1	0	0	
			Eye pain	1	0	0	
			Lens disorder	2	0	2	
			Glaucoma	1	0	0	
			Blepharitis	2	0	1	
			Blepharospasm	1	0	0	
			Oculogyric crisis	9	0	3	
			Miosis	1	0	1	
			Mydriasis	1	0	0	
			Retinal pigmentation	1	0	0	
			Visual acuity reduced	1	0	0	
			Visual impairment	5	0	1	
			Eye disorders	31	0	8	
		Gastrointestinal disorders	Pancreatitis	2	0	0	
			Gastrointestinal haemorrhage	1	0	0	
			Haematemesis	2	0	0	
			Melaena	1	0	0	
			Constipation	2	0	2	
			Megacolon	1	0	1	
			Faeces discoloured	1	0	0	
			Abdominal pain	6	0	3	
			Dysphagia	3	0	0	
			Faecal incontinence	1	0	0	
			Nausea	15	1	3	
			Vomiting	11	1	6	
			Cheilitis	2	0	1	
			Aphthous stomatitis	1	0	0	
			Mouth ulceration	2	0	0	
			Dry mouth	6	0	5	
			Salivary hypersecretion	4	0	0	
			Glossitis	1	0	1	
			Swollen tongue	1	0	1	
			Tongue oedema	7	0	5	
			Gastrointestinal disorders	70	2	28	
			General disorders and administration site conditions	Injection site inflammation	1	0	1
				Injection site necrosis	1	0	1
		Injection site reaction		6	0	5	
		Hypothermia		2	0	2	
		Hyperpyrexia		1	0	0	
Pyrexia	26	2		3			

Chlorpromazine hydrochloride to end January 2009

			Case Group	Death Outcomes	Sole		
Medicine	Reaction Count	General disorders and administration site conditions	Sudden death	5	5	0	
			Fatigue	3	1	0	
			Malaise	3	0	2	
			Gait disturbance	1	0	1	
			Influenza like illness	1	0	0	
			Irritability	1	0	1	
			Face oedema	11	0	7	
			Oedema	3	0	2	
			Oedema peripheral	5	0	4	
			Chest pain	1	0	0	
			Pain	3	0	1	
			Chills	1	0	0	
			Feeling abnormal	1	0	0	
			Thirst	1	0	1	
			Drug ineffective	5	1	3	
			Paradoxical drug reaction	1	0	0	
			Drug withdrawal syndrome neonatal	1	0	0	
			General disorders and administration site conditions	84	9	34	
			Hepatobiliary disorders	Hepatitis cholestatic	28	0	18
				Jaundice	33	1	17
		Jaundice cholestatic		1	0	0	
		Hepatic function abnormal		23	0	7	
		Hepatic failure		1	1	0	
		Hepatic cirrhosis		1	0	1	
		Hepatomegaly		2	0	1	
		Hepatitis		11	0	2	
		Hepatocellular injury		1	0	0	
		Hepatobiliary disorders		101	2	46	
		Immune system disorders	Anaphylactoid reaction	1	0	1	
			Immune system disorders	1	0	1	
		Infections and infestations	Cellulitis	2	0	2	
			Candidiasis	1	0	1	
			Abscess	1	0	1	
			Injection site abscess	4	0	3	
			Pneumonia	1	1	0	
			Sepsis	4	2	0	
			Rash pustular	4	0	3	
			Pharyngitis	4	1	2	
			Rhinitis	2	0	0	
			Upper respiratory tract infection	1	0	0	
			Infections and infestations	24	4	12	

Chlorpromazine hydrochloride to end January 2009

				Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Injury, poisoning and procedural complications	Drug exposure during pregnancy	2	0	0	
			Fall	2	0	1	
			Injury, poisoning and procedural complications	4	0	1	
		Investigations	Ejection fraction decreased	1	0	0	
			Electrocardiogram QT prolonged	2	0	0	
			Electrocardiogram abnormal	4	0	3	
			Blood pressure decreased	1	0	0	
			Blood thyroid stimulating hormone increased	1	0	1	
			Blood creatine phosphokinase increased	13	0	3	
			Troponin increased	1	0	0	
			Blood alkaline phosphatase increased	1	0	0	
			Prothrombin level decreased	2	0	0	
			Red blood cell sedimentation rate increased	2	0	0	
			Hepatic enzyme increased	1	0	0	
			Liver function test abnormal	6	0	2	
			Oxygen saturation decreased	1	0	0	
			Weight decreased	1	0	1	
			Weight increased	2	0	1	
			Urine analysis abnormal	1	0	1	
			Investigations	40	0	12	
			Metabolism and nutrition disorders	Ketosis	1	0	0
				Anorexia	7	1	3
		Obesity		1	0	0	
		Hypocalcaemia		1	0	0	
		Polydipsia		1	0	0	
		Hyperkalaemia		1	1	0	
		Hypokalaemia		3	0	0	
		Hyponatraemia		9	1	2	
		Hyperglycaemia		2	1	0	
		Metabolism and nutrition disorders		26	4	5	
		Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	2	0	1	
			Arthralgia	2	0	0	
			Myalgia	2	0	0	
			Muscle twitching	5	0	1	
			Torticollis	2	0	1	
			Muscle necrosis	1	0	1	
			Rhabdomyolysis	3	0	1	
			Musculoskeletal stiffness	1	0	0	
			Musculoskeletal and connective tissue disorders	18	0	5	

Chlorpromazine hydrochloride to end January 2009

Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer female	1	0	0
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0	0
	Nervous system disorders	Cerebral haemorrhage	2	2	0	
		Tongue paralysis	2	0	0	
		Encephalopathy	2	0	0	
		Headache	5	0	1	
		Brain oedema	1	1	0	
		Amnesia	1	0	0	
		Disturbance in attention	2	0	2	
		Akathisia	3	0	0	
		Dyskinesia	11	0	2	
		Extrapyramidal disorder	20	0	4	
		Hyperkinesia	8	0	3	
		Hypokinesia	1	0	0	
		Tardive dyskinesia	11	0	5	
		Dystonia	27	0	7	
		Hemiparesis	1	0	1	
		Cogwheel rigidity	1	0	0	
		Tremor	13	0	4	
		Hyperreflexia	1	0	0	
		Ataxia	5	0	2	
		Coordination abnormal	1	0	1	
		Coma	4	0	3	
		Altered state of consciousness	1	0	0	
		Consciousness fluctuating	4	1	1	
		Depressed level of consciousness	2	0	1	
		Lethargy	1	0	1	
		Loss of consciousness	1	0	0	
		Sedation	1	0	1	
		Somnolence	17	0	8	
		Syncope	11	0	4	
		Dizziness	10	0	6	
		Unresponsive to stimuli	2	0	1	
		Paraesthesia	6	0	3	
		Dysgeusia	2	0	1	
		Hypoaesthesia	1	0	1	
		Sensory disturbance	1	0	0	
		Dysarthria	5	0	3	
		Speech disorder	2	0	1	
		Hypertonia	14	0	5	
		Neuroleptic malignant syndrome	19	1	4	
		Serotonin syndrome	2	0	0	

Chlorpromazine hydrochloride to end January 2009

			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Nervous system disorders	Neuropathy peripheral	1	0	0
			Convulsion neonatal	1	0	0
			Grand mal convulsion	5	0	1
			Convulsion	7	0	1
			Nervous system disorders	238	5	78
		Pregnancy, puerperium and perinatal conditions	Intra-uterine death	1	1	1
			Foetal growth retardation	2	0	0
			Small for dates baby	1	0	0
			Neonatal disorder	2	0	0
			Pregnancy, puerperium and perinatal conditions	6	1	1
		Psychiatric disorders	Agitation	19	0	7
			Anxiety	5	0	1
			Nervousness	1	0	0
			Fear	1	0	0
			Catatonia	2	0	0
			Restlessness	1	0	0
			Confusional state	34	0	8
			Disorientation	1	0	1
			Delirium	3	0	0
			Depression	4	0	0
			Depersonalisation	1	0	1
			Persecutory delusion	1	0	0
			Hallucination	6	0	2
			Thinking abnormal	3	0	1
			Mania	1	0	0
			Frustration	1	0	0
			Aggression	2	0	0
			Homicidal ideation	1	0	0
			Personality change	1	0	0
			Withdrawal syndrome	1	0	0
			Psychotic disorder	4	0	2
			Libido decreased	1	0	0
			Insomnia	3	0	1
			Nightmare	3	0	2
			Completed suicide	1	1	0
			Intentional self-injury	1	0	0
			Suicidal ideation	2	0	0
		Suicide attempt	5	0	1	
		Psychiatric disorders	109	1	27	
		Renal and urinary disorders	Tubulointerstitial nephritis	1	1	0
			Anuria	1	0	0
			Renal failure acute	3	2	0

Chlorpromazine hydrochloride to end January 2009

			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Renal and urinary disorders	Renal impairment	5	1	0
			Renal tubular necrosis	1	0	0
			Dysuria	2	0	1
			Urinary incontinence	4	0	1
			Urinary retention	7	0	4
			Choluria	1	0	1
			Haematuria	3	0	1
			Myoglobinuria	1	0	0
			Renal and urinary disorders	29	4	8
		Reproductive system and breast disorders	Breast enlargement	1	0	1
			Galactorrhoea	1	0	1
			Erectile dysfunction	1	0	1
			Priapism	7	0	4
			Reproductive system and breast disorders	10	0	7
		Respiratory, thoracic and mediastinal disorders	Wheezing	1	0	0
			Pulmonary oedema	1	0	0
			Pulmonary hypertension	1	0	0
			Apnoea	1	0	1
			Dyspnoea	10	1	5
			Hyperventilation	1	0	0
			Respiratory depression	1	0	0
			Cough	1	0	0
			Productive cough	1	1	0
			Dysphonia	1	0	0
			Oropharyngeal pain	1	0	0
			Throat tightness	3	0	1
			Epistaxis	3	0	1
			Sinus congestion	1	0	1
			Respiratory, thoracic and mediastinal disorders	27	2	9
		Skin and subcutaneous tissue disorders	Angioedema	2	0	1
			Periorbital oedema	1	0	1
			Urticaria	14	0	11
			Blister	1	0	1
			Dermatitis bullous	4	0	1
			Erythema multiforme	1	0	0
			Toxic epidermal necrolysis	2	1	0
			Dry skin	1	0	1
			Skin discolouration	3	0	2
			Skin disorder	1	0	0
			Skin necrosis	1	0	1
		Skin swelling	1	0	1	

Chlorpromazine hydrochloride to end January 2009

Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Skin and subcutaneous tissue disorders	Swelling face	1	0	1
			Dermatitis	2	0	2
			Dermatitis contact	3	0	3
			Eczema	1	0	1
			Seborrhoeic dermatitis	1	0	1
			Erythema	1	0	1
			Rash erythematous	11	0	3
			Skin exfoliation	1	0	1
			Rash papular	1	0	0
			Photosensitivity reaction	21	0	10
			Pruritus	39	0	19
			Dermatitis psoriasiform	1	0	1
			Rash	36	0	14
			Rash macular	1	0	0
			Rash maculo-papular	32	2	17
			Rash morbilliform	3	0	1
			Melanosis	1	0	1
			Skin ulcer	3	0	0
			Acne	1	0	1
			Alopecia	1	0	0
			Cold sweat	1	0	1
			Hyperhidrosis	6	0	3
			Seborrhoea	2	0	0
		Purpura	6	1	2	
		Skin and subcutaneous tissue disorders	208	4	103	
		Social circumstances	Immobile	1	0	0
			Social circumstances	1	0	0
		Vascular disorders	Circulatory collapse	2	0	1
			Hypotension	32	0	13
			Orthostatic hypotension	12	0	6
			Flushing	4	0	2
			Pallor	4	0	2
			Hypertension	4	0	2
			Vascular disorders	58	0	26
		Reaction	1211	47	435	