

## clomipramine hydrochloride to end January 2009

				Case Group	Death Outcomes	Sole
Case Count				182	0	133
Medicine	Reaction Count	Blood and lymphatic system disorders	Thrombocytopenia	2	0	1
			Agranulocytosis	2	0	0
			Blood and lymphatic system disorders	4	0	1
		Cardiac disorders	Tachycardia	8	0	6
			Atrial fibrillation	1	0	1
			Ventricular tachycardia	1	0	0
			Palpitations	4	0	3
			Left ventricular failure	1	0	0
			Cardiomyopathy	2	0	1
			Cardiac disorders	17	0	11
			Ear and labyrinth disorders	Deafness	1	0
		Ear and labyrinth disorders		1	0	1
		Endocrine disorders	Hyperprolactinaemia	1	0	0
			Endocrine disorders	1	0	0
		Eye disorders	Mydriasis	1	0	1
			Accommodation disorder	1	0	1
			Visual impairment	5	0	4
			Optic neuropathy	1	0	0
			Eye disorders	8	0	6
		Gastrointestinal disorders	Melaena	1	0	1
			Diarrhoea	4	0	4
			Constipation	4	0	0
			Dyspepsia	1	0	1
			Eructation	1	0	1
			Abdominal pain	4	0	3
			Dysphagia	2	0	1
			Nausea	28	0	26
			Vomiting	15	0	13
			Peptic ulcer	1	0	1
			Hypoaesthesia oral	1	0	1
			Mouth ulceration	1	0	0
			Dry mouth	8	0	4
			Glossitis	1	0	1
			Tongue oedema	2	0	2
			Gastrointestinal disorders	74	0	59
		General disorders and administration site conditions	Application site reaction	1	0	1
Pyrexia	6		0	2		
Fatigue	5		0	5		
Malaise	5		0	4		
Concomitant disease aggravated	1		0	1		
Face oedema	1		0	1		

## clomipramine hydrochloride to end January 2009

Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>General disorders and administration site conditions</b>	Oedema	3	0	1
			Chills	2	0	1
			Thirst	1	0	0
			Drug withdrawal syndrome neonatal	1	0	1
			General disorders and administration site conditions	26	0	17
		<b>Hepatobiliary disorders</b>	Hepatic function abnormal	8	0	6
			Hepatitis	4	0	2
			Hepatocellular injury	1	0	1
			Hepatobiliary disorders	13	0	9
		<b>Infections and infestations</b>	Pharyngitis	1	0	1
			Infections and infestations	1	0	1
		<b>Investigations</b>	Blood creatine phosphokinase increased	1	0	0
			Blood glucose increased	1	0	1
			Weight increased	3	0	3
			Drug level above therapeutic	1	0	0
			Drug level increased	1	0	0
			Blood phosphorus decreased	1	0	1
			Investigations	8	0	5
			<b>Metabolism and nutrition disorders</b>	Acidosis	1	0
		Anorexia	5	0	5	
		Hypokalaemia	1	0	1	
		Hyponatraemia	3	0	3	
		Alcohol intolerance	1	0	0	
		Hyperglycaemia	1	0	0	
		<b>Metabolism and nutrition disorders</b>	Metabolism and nutrition disorders	12	0	9
		<b>Musculoskeletal and connective tissue disorders</b>	Arthralgia	3	0	2
			Myalgia	5	0	2
			Muscle spasms	3	0	2
			Muscle twitching	3	0	2
			Rhabdomyolysis	2	0	0
			Mobility decreased	1	0	0
			Musculoskeletal and connective tissue disorders	17	0	8
		<b>Nervous system disorders</b>	Cerebrovascular disorder	1	0	0
			Headache	7	0	6
			Amnesia	2	0	1
			Memory impairment	1	0	1
			Cognitive disorder	2	0	1
			Choreoathetosis	1	0	1
			Dyskinesia	2	0	2
			Extrapyramidal disorder	1	0	1
			Hyperkinesia	1	0	1

## clomipramine hydrochloride to end January 2009

Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Nervous system disorders	Dystonia	3	0	2
			Tremor	19	0	15
			Hyperreflexia	1	0	1
			Ataxia	2	0	2
			Coordination abnormal	2	0	1
			Nystagmus	1	0	1
			Coma	1	0	0
			Somnolence	4	0	3
			Syncope	7	0	3
			Dizziness	13	0	11
			Paraesthesia	10	0	8
			Dysgeusia	1	0	0
			Hypoaesthesia	1	0	1
			Sensory disturbance	1	0	0
			Incoherent	1	0	1
			Speech disorder	2	0	1
			Hypertonia	7	0	4
			Neuroleptic malignant syndrome	1	0	0
			Serotonin syndrome	4	0	0
			Neuropathy peripheral	2	0	1
			Grand mal convulsion	1	0	1
			Convulsion	8	0	2
			Drug withdrawal convulsions	1	0	1
		Nervous system disorders	111	0	73	
		Pregnancy, puerperium and perinatal conditions	Intra-uterine death	1	0	0
			Pregnancy, puerperium and perinatal conditions	1	0	0
		Psychiatric disorders	Agitation	11	0	6
			Anxiety	7	0	6
			Nervousness	4	0	4
			Panic attack	1	0	1
			Bruxism	1	0	1
			Confusional state	6	0	5
			Delirium	2	0	1
			Depression	2	0	2
			Depersonalisation	1	0	1
			Delusion	1	0	1
			Hallucination	4	0	4
			Thinking abnormal	1	0	1
			Mania	4	0	2
			Aggression	1	0	1
			Personality change	1	0	1
		Abnormal behaviour	1	0	1	

## clomipramine hydrochloride to end January 2009

Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>Psychiatric disorders</b>	Withdrawal syndrome	4	0	4
			Psychotic disorder	2	0	2
			Anorgasmia	1	0	1
			Libido decreased	1	0	1
			Insomnia	8	0	7
			Nightmare	3	0	2
			Sleep disorder	1	0	1
			Suicidal ideation	1	0	1
			<b>Psychiatric disorders</b>	<b>69</b>	<b>0</b>	<b>57</b>
		<b>Renal and urinary disorders</b>	Renal impairment	1	0	0
			Micturition disorder	1	0	1
			Urinary retention	2	0	1
			Haematuria	1	0	1
			Polyuria	1	0	1
			<b>Renal and urinary disorders</b>	<b>6</b>	<b>0</b>	<b>4</b>
		<b>Reproductive system and breast disorders</b>	Breast engorgement	1	0	1
			Galactorrhoea	5	0	5
			Menstrual disorder	1	0	1
			Peyronie's disease	1	0	0
			Ejaculation failure	9	0	7
			Erectile dysfunction	2	0	1
			<b>Reproductive system and breast disorders</b>	<b>19</b>	<b>0</b>	<b>15</b>
		<b>Respiratory, thoracic and mediastinal disorders</b>	Asthma	1	0	1
			Wheezing	1	0	1
			Neonatal respiratory distress syndrome	1	0	0
			Dyspnoea	3	0	2
			Hyperventilation	1	0	0
			Cough	1	0	1
			Yawning	1	0	1
			<b>Respiratory, thoracic and mediastinal disorders</b>	<b>9</b>	<b>0</b>	<b>6</b>
		<b>Skin and subcutaneous tissue disorders</b>	Periorbital oedema	2	0	2
			Urticaria	3	0	2
			Skin disorder	1	0	1
			Rash erythematous	1	0	1
			Pruritus	5	0	5
			Fixed eruption	1	0	1
			Rash	7	0	6
			Rash maculo-papular	2	0	2
			Systemic lupus erythematosus rash	1	0	0
			Alopecia	3	0	3
			<b>Hyperhidrosis</b>	<b>22</b>	<b>0</b>	<b>16</b>

## clomipramine hydrochloride to end January 2009

				Case Group	Death Outcomes	Sole
<b>Medicine</b>	<b>Reaction Count</b>	<b>Skin and subcutaneous tissue disorders</b>	<b>Night sweats</b>	1	0	1
			<b>Hair texture abnormal</b>	1	0	1
			<b>Rosacea</b>	1	0	1
			<b>Purpura</b>	6	0	5
			<b>Skin and subcutaneous tissue disorders</b>	57	0	47
		<b>Surgical and medical procedures</b>	<b>Drug therapy changed</b>	1	0	1
			<b>Therapy regimen changed</b>	1	0	0
			<b>Surgical and medical procedures</b>	2	0	1
		<b>Vascular disorders</b>	<b>Hypotension</b>	5	0	2
			<b>Orthostatic hypotension</b>	6	0	3
			<b>Flushing</b>	6	0	4
			<b>Hot flush</b>	1	0	1
			<b>Hypertension</b>	1	0	1
			<b>Vascular disorders</b>	19	0	11
			<b>Reaction</b>	475	0	341