

## Zuclophenthixol acetate, decanoate and dihydrochloride to end January 2009

Case Count				Case Group	Death Outcomes	Sole
				139	4	59
Medicine	Reaction Count	Blood and lymphatic system disorders	Coagulopathy	1	0	1
			Factor VIII inhibition	1	0	1
			Leukopenia	1	0	0
			Neutropenia	1	0	0
			Blood and lymphatic system disorders	4	0	2
		Cardiac disorders	Tachycardia	6	0	1
			Atrial fibrillation	1	0	1
			Sinus tachycardia	1	0	0
			Cardiac arrest	2	0	0
			Cardiac disorder	1	0	0
			Cyanosis	1	0	0
			Cardiac failure	1	0	1
			Cardiomyopathy	2	0	0
			Myocarditis	2	0	0
			Cardiac disorders	17	0	3
		Congenital, familial and genetic disorders	Congenital foot malformation	1	0	0
			Congenital, familial and genetic disorders	1	0	0
		Eye disorders	Blepharospasm	1	0	0
			Oculogyric crisis	5	0	1
			Myopia	1	0	0
			Vision blurred	1	0	1
			Eye disorders	8	0	2
		Gastrointestinal disorders	Abdominal pain	1	0	0
			Dysphagia	1	0	1
			Nausea	2	0	1
			Vomiting	4	0	0
			Oral disorder	1	0	0
			Salivary hypersecretion	1	0	0
			Swollen tongue	3	0	2
			Tongue oedema	4	0	2
			Gastrointestinal disorders	17	0	6
		General disorders and administration site conditions	Injection site reaction	5	0	4
			Hypothermia	1	0	0
			Pyrexia	4	1	1
Death	1		1	1		
Sudden death	1		1	0		
Asthenia	1		0	1		
Fatigue	2		0	2		
Gait disturbance	3		0	3		

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>General disorders and administration site conditions</b>	Face oedema	1	0	1
			Chest pain	2	0	0
			Feeling abnormal	2	0	2
			<b>General disorders and administration site conditions</b>	<b>23</b>	<b>3</b>	<b>15</b>
		<b>Hepatobiliary disorders</b>	Hyperbilirubinaemia	1	0	0
			Hepatic function abnormal	2	0	0
			Hepatosplenomegaly neonatal	1	0	0
			<b>Hepatobiliary disorders</b>	<b>4</b>	<b>0</b>	<b>0</b>
		<b>Infections and infestations</b>	Cellulitis	1	0	1
			Abscess	2	0	1
			Injection site abscess	1	0	1
			Pneumonia	1	0	0
			Sepsis	1	0	0
			<b>Infections and infestations</b>	<b>6</b>	<b>0</b>	<b>3</b>
		<b>Injury, poisoning and procedural complications</b>	Overdose	1	0	0
			<b>Injury, poisoning and procedural complications</b>	<b>1</b>	<b>0</b>	<b>0</b>
		<b>Investigations</b>	Blood pressure decreased	1	0	0
			Blood pressure increased	1	0	0
			Blood creatine phosphokinase increased	5	0	4
			Troponin T increased	1	0	0
			Eosinophil count increased	1	0	0
			Oxygen saturation decreased	1	0	0
			Weight increased	2	0	1
			C-reactive protein increased	1	0	0
			Semen analysis abnormal	1	0	1
			Drug level increased	1	1	0
			<b>Investigations</b>	<b>15</b>	<b>1</b>	<b>6</b>
		<b>Metabolism and nutrition disorders</b>	Tetany	2	0	1
			Diabetes mellitus	2	0	1
			Hyperammonaemia	1	0	0
			<b>Metabolism and nutrition disorders</b>	<b>5</b>	<b>0</b>	<b>2</b>
		<b>Musculoskeletal and connective tissue disorders</b>	Arthritis	2	0	2
			Arthralgia	2	0	1
			Joint stiffness	1	0	1
			Myalgia	2	0	1
			Muscle rigidity	1	0	0
			Torticollis	2	0	2
			Trismus	1	0	1
			<b>Rhabdomyolysis</b>	<b>1</b>	<b>0</b>	<b>0</b>

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole		
		Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	8	0	5	
			Back pain	1	0	1	
			Musculoskeletal and connective tissue disorders	21	0	14	
		Nervous system disorders	Cerebral haemorrhage neonatal	1	0	0	
			Dementia	1	0	0	
			Akathisia	5	0	0	
			Dyskinesia	6	0	2	
			Extrapyramidal disorder	8	0	4	
			Hyperkinesia	2	0	2	
			Tardive dyskinesia	1	0	1	
			Dystonia	29	0	11	
			Paralysis	1	0	0	
			Parkinsonism	1	0	1	
			Tremor	3	0	0	
			Ataxia	2	0	2	
			Balance disorder	1	0	1	
			Coordination abnormal	1	0	0	
			Coma	1	0	0	
			Aphasia	1	0	0	
			Consciousness fluctuating	1	0	0	
			Depressed level of consciousness	1	0	0	
			Sedation	1	1	1	
			Somnolence	4	0	2	
			Syncope	3	0	0	
			Dizziness	2	0	1	
			Drooling	1	0	0	
			Dysarthria	1	0	1	
			Speech disorder	3	0	1	
			Hypertonia	8	0	3	
			Hypotonia	1	0	0	
			Neuroleptic malignant syndrome	5	0	3	
			Grand mal convulsion	2	0	0	
			Convulsion	4	0	1	
			Nervous system disorders	101	1	37	
			Pregnancy, puerperium and perinatal conditions	Weight decrease neonatal	1	0	0
				Pregnancy, puerperium and perinatal conditions	1	0	0
		Psychiatric disorders	Agitation	4	0	2	
			Nervousness	1	0	0	
			Catatonia	3	0	0	
			Confusional state	3	0	3	

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Psychiatric disorders	Disorientation	1	0	1
			Delirium	2	0	1
			Depression	1	0	1
			Depersonalisation	1	0	1
			Aggression	8	0	2
			Homicidal ideation	4	0	1
			Nicotine dependence	1	0	0
			Completed suicide	1	1	1
			Suicidal ideation	5	0	0
			Suicide attempt	4	0	0
			<b>Psychiatric disorders</b>	<b>39</b>	<b>1</b>	<b>13</b>
		Renal and urinary disorders	Renal impairment	1	0	0
			Urinary incontinence	1	0	1
			<b>Renal and urinary disorders</b>	<b>2</b>	<b>0</b>	<b>1</b>
		Reproductive system and breast disorders	Priapism	1	0	0
			Sexual dysfunction	2	0	2
			<b>Reproductive system and breast disorders</b>	<b>3</b>	<b>0</b>	<b>2</b>
		Respiratory, thoracic and mediastinal disorders	Asthma	1	0	1
			Obstructive airways disorder	1	0	0
			Pneumonia aspiration	1	0	1
			Infantile apnoeic attack	1	0	0
			Pulmonary embolism	2	0	1
			Dyspnoea	8	0	6
			Hypoxia	1	0	0
			Cough	1	0	0
			Laryngospasm	3	0	2
			Stridor	1	0	1
			<b>Respiratory, thoracic and mediastinal disorders</b>	<b>20</b>	<b>0</b>	<b>12</b>
		Skin and subcutaneous tissue disorders	Urticaria	1	0	1
			Erythema multiforme	1	0	0
			Rash erythematous	3	0	1
			Pruritus	1	0	1
			Rash	3	0	3
			Rash maculo-papular	2	0	1
			Alopecia	1	0	0
			Hyperhidrosis	1	0	0
			<b>Skin and subcutaneous tissue disorders</b>	<b>13</b>	<b>0</b>	<b>7</b>
		Surgical and medical procedures	Therapy regimen changed	2	0	0
			<b>Surgical and medical procedures</b>	<b>2</b>	<b>0</b>	<b>0</b>

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Vascular disorders	Circulatory collapse	1	0	1
			Hypotension	9	0	3
			Orthostatic hypotension	2	0	0
			Deep vein thrombosis	1	0	0
			Haematoma	1	0	1
			Hypertension	1	0	0
			Vascular disorders	15	0	5
		Reaction	318	6	130	