			Case Group	Death Outcomes	Sole
Case Count			122	2	111
Reaction Count	Blood and lymphatic system disorders	Neutropenia	1	0	1
		Blood and lymphatic system disorders	1	0	1
	Cardiac disorders	Tachycardia	2	0	2
		Palpitations	1	0	1
		Cardiac failure	1	0	1
		Cardiac disorders	4	0	4
	Endocrine disorders	Hyperprolactinaemia	6	0	6
		Endocrine disorders	6	0	6
	Eye disorders	Blepharospasm	1	0	1
		Eye movement disorder	2	0	2
		Oculogyric crisis	3	0	2
		Mydriasis	1	0	1
		Eye disorders	7	0	6
	Gastrointestinal disorders	Flatulence	1	0	1
		Abdominal pain upper	2	0	2
		Dysphagia	2	0	2
		Nausea	1	0	1
		Lip dry	1	0	1
		Salivary hypersecretion	1	0	1
		Swollen tongue	1	0	1
		Gastrointestinal disorders	9	0	9
	General disorders and administration site conditions	Injection site pain	1	0	1
		Injection site swelling	1	0	1
		Pyrexia	1	0	1
		Malaise	5	1	4
		Gait disturbance	1	0	1
		Condition aggravated	4	0	4
		Irritability	2	0	2
		Oedema peripheral	1	0	1
		Chest pain	2	0	2
		Drug effect decreased	1	0	0
		Drug ineffective	7	1	6

7 Outcome Description

(Causality possible, Causality probable, Causality certain)

Suspect Type

Suspect Code

T Case Group

₮ <u>GM</u>

			Case Group	Death Outcomes	Sole
Reaction Count	General disorders and administration site	Therapeutic response decreased	1	0	1
	conditions	Product quality issue	8	0	8
		General disorders and administration site conditions	35	2	32
	Hepatobiliary disorders	Hepatic function abnormal	1	0	1
		Hepatobiliary disorders	1	0	1
	Immune system disorders	Hypersensitivity	1	0	1
		Immune system disorders	1	0	1
	Injury, poisoning and procedural	Hip fracture	1	0	1
	complications	Toxicity to various agents	1	0	0
		Fall	1	0	1
		Inappropriate schedule of drug administration	1	0	1
		Incorrect dose administered	1	0	1
		Wrong technique in drug usage process	1	0	1
		Intentional overdose	1	0	1
		Overdose	1	0	1
		Injury, poisoning and procedural complications	8	0	7
	Investigations	Blood prolactin increased	10	0	9
		Blood creatine phosphokinase increased	2	0	1
		Neutrophil count decreased	1	0	1
		White blood cell count decreased	2	0	2
		Liver function test abnormal	2	0	1
		Blood glucose decreased	1	0	1
		Electroencephalogram abnormal	1	0	0
		Weight increased	4	0	4
		Investigations	23	0	19
	Metabolism and nutrition disorders	Diabetes mellitus	1	0	1
		Metabolism and nutrition disorders	1	0	1
	Musculoskeletal and connective tissue disorders	Arthralgia	1	0	1
		Muscle disorder	1	0	1
		Muscle rigidity	1	0	0
		Trismus	1	0	1
		Musculoskeletal stiffness	3	0	3

7 Outcome Description

(Causality possible, Causality probable, Causality certain)

Suspect Type

Suspect Code

T Case Group

₮ <u>GM</u>

			Case Group	Death Outcomes	Sole
Reaction	Musculoskeletal and connective tissue disorders	Neck pain	1	0	1
Count		Pain in extremity	1	0	1
		Musculoskeletal and connective tissue disorders	9	0	8
	Nervous system disorders	Cerebrovascular accident	1	0	1
		Facial spasm	1	0	1
		Headache	2	0	2
		Memory impairment	1	0	1
		Cognitive disorder	1	0	1
		Mental impairment	4	1	2
		Akathisia	5	0	4
		Extrapyramidal disorder	6	0	5
		Movement disorder	1	0	1
		Tardive dyskinesia	4	0	4
		Dystonia	3	0	3
		Masked facies	1	0	1
		Parkinsonism	5	0	4
		Tremor	4	0	4
		Ataxia	1	0	0
		Sedation	5	0	5
		Somnolence	3	0	2
		Syncope	2	0	2
		Dizziness	5	0	5
		Drooling	1	0	1
		Paraesthesia	2	0	2
		Dysarthria	1	0	1
		Speech disorder	1	0	1
		Neuroleptic malignant syndrome	1	0	0
		Convulsion	1	0	0
		Brain injury	1	1	0
		Nervous system disorders	63	2	53
	Psychiatric disorders	Agitation	6	0	6
		Anxiety	2	0	2

7 Outcome Description

(Causality possible, Causality probable, Causality certain)

Suspect Type

Suspect Code

T Case Group

₮ <u>GM</u>

			Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Nervousness	1	0	0
		Panic attack	1	0	1
		Bruxism	1	0	1
		Confusional state	1	0	1
		Disorientation	1	0	1
		Depression	2	0	2
		Delusion	1	0	1
		Hallucination, auditory	2	1	1
		Thinking abnormal	1	0	1
		Eating disorder	1	0	1
		Mania	2	0	2
		Apathy	1	0	1
		Aggression	7	1	6
		Abnormal behaviour	1	1	0
		Mental status changes	2	0	1
		Psychotic disorder	6	0	4
		Schizophrenia	7	0	6
		Insomnia	3	0	3
		Completed suicide	1	1	1
		Suicidal ideation	1	0	0
		Psychiatric disorders	51	4	42
	Renal and urinary disorders	Nephropathy	1	0	1
		Incontinence	1	0	1
		Renal and urinary disorders	2	0	2
	Reproductive system and breast disorders	Gynaecomastia	1	0	1
		Galactorrhoea	3	0	3
		Amenorrhoea	1	0	1
		Sexual dysfunction	1	0	1
		Semen discolouration	1	0	1
		Reproductive system and breast disorders	7	0	7
	Respiratory, thoracic and mediastinal disorders	Dyspnoea	1	0	1
		Asphyxia	1	1	0



(Causality possible, Causality probable, Causality certain)

Suspect Type

Suspect Code

T Case Group

₮ <u>GM</u>

			Case Group	Death Outcomes	Sole
Reaction Count	Respiratory, thoracic and mediastinal disorders	Respiratory, thoracic and mediastinal disorders	2	1	1
	Skin and subcutaneous tissue disorders	Urticaria	1	0	1
		Hypoaesthesia facial	1	0	1
		Seborrhoeic dermatitis	1	0	0
		Rash erythematous	1	0	1
		Pruritus	1	0	1
		Rash	1	0	1
		Skin and subcutaneous tissue disorders	6	0	5
	Social circumstances	Treatment noncompliance	1	0	0
		Social circumstances	1	0	0
	Surgical and medical procedures	Off label use	2	0	2
		Therapy regimen changed	2	0	2
		Surgical and medical procedures	4	0	4
	Vascular disorders	Hypotension	2	0	2
		Orthostatic hypotension	1	0	1
		Hot flush	1	0	1
		Hypertension	2	0	2
		Vascular disorders	6	0	6
	Reaction		247	9	215

Nows are suppressed based on zeros and empty cells for Case Group

Y Outcome Description

(Causality possible, Causality probable, Causality certain)

Suspect Type

Suspect Code

T Case Group