			Case Group	Death Outcomes	Sole
Case Count			117	3	80
Reaction Count	Blood and lymphatic system disorders	Anaemia	1	0	0
		Pancytopenia	1	0	1
		Splenomegaly	1	0	0
		Eosinophilia	2	0	1
		Leukocytosis	1	0	0
		Leukopenia	2	0	1
		Febrile neutropenia	1	0	1
		Neutropenia	3	0	0
		Blood and lymphatic system disorders	12	0	4
	Cardiac disorders	Tachycardia	1	0	0
		Myocardial ischaemia	1	1	0
		Cardiomyopathy	3	0	0
		Myocarditis	1	0	0
		Cardiac disorders	6	1	0
	Endocrine disorders	Hyperprolactinaemia	1	0	0
		Endocrine disorders	1	0	0
	Eye disorders	Periorbital oedema	1	0	1
		Visual impairment	2	0	1
		Eye disorders	3	0	2
	Gastrointestinal disorders	Nausea	3	0	2
		Vomiting	2	0	1
		Salivary hypersecretion	1	0	0
		Tongue oedema	1	0	1
		Gastrointestinal disorders	7	0	4
	General disorders and administration site conditions	Injection site abscess sterile	1	0	1
		Injection site inflammation	11	0	11
		Injection site pain	4	0	4
		Injection site reaction	32	0	32
		Pyrexia	4	0	2
		Death	1	1	0
		Asthenia	1	0	1
		Fatigue	2	0	2



(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 conditions	Malaise	3	0	1
		Gait disturbance	5	0	4
		Influenza like illness	1	0	0
		Face oedema	3	0	2
		Oedema	4	0	4
		Chest pain	1	0	0
		Pain	3	0	3
		General disorders and administration site conditions	76	1	67
	Hepatobiliary disorders	Hepatic function abnormal	2	0	0
		Hepatomegaly	1	0	0
		Hepatic steatosis	1	0	0
		Hepatobiliary disorders	4	0	0
	Immune system disorders	Anaphylactoid reaction	2	0	2
		Immune system disorders	2	0	2
	Infections and infestations	Cellulitis	2	0	2
		Injection site abscess	2	0	2
		Upper respiratory tract infection	1	0	0
		Cystitis	1	0	1
		Infections and infestations	6	0	5
	Injury, poisoning and procedural complications	Toxicity to various agents	1	1	0
		Overdose	1	0	0
		Injury, poisoning and procedural complications	2	1	0
	Investigations	Blood creatine phosphokinase increased	3	0	1
		Quality of life decreased	2	0	2
		Weight decreased	1	0	1
		Weight increased	3	0	2
		Glomerular filtration rate decreased	1	0	0
		Investigations	10	0	6
	Metabolism and nutrition disorders	Decreased appetite	1	0	1
		Hyponatraemia	1	0	0
		Dehydration	1	0	0
		Hypoproteinaemia	1	0	0

7 Outcome Description

(Causality possible, Causality probable, Causality certain)

Suspect Type

Y Suspect Code

T Case Group

₮ <u>GM</u>

			Case Group	Death Outcomes	Sole
Reaction Count	Metabolism and nutrition disorders	Metabolism and nutrition disorders	4	0	1
	Musculoskeletal and connective tissue	Arthralgia	1	0	0
	disorders	Joint stiffness	1	0	0
		Muscle rigidity	2	0	1
		Musculoskeletal stiffness	3	0	3
		Pain in extremity	1	0	1
		Musculoskeletal and connective tissue disorders	8	0	5
	Nervous system disorders	Headache	1	0	1
		Mental impairment	1	0	1
		Akathisia	5	0	4
		Akinesia	1	0	1
		Extrapyramidal disorder	7	0	4
		Hyperkinesia	1	0	1
		Tardive dyskinesia	6	0	4
		Paralysis	1	0	1
		Parkinsonism	1	0	1
		Tremor	5	0	3
		Ataxia	1	0	0
		Lethargy	2	0	2
		Syncope	1	0	1
		Paraesthesia	1	0	0
		Dysarthria	1	0	1
		Speech disorder	2	0	1
		Hypertonia	3	0	2
		Neuroleptic malignant syndrome	3	0	1
		Nervous system disorders	43	0	29
	Pregnancy, puerperium and perinatal conditions	Foetal growth restriction	1	0	1
		Pregnancy, puerperium and perinatal conditions	1	0	1
	Psychiatric disorders	Agitation	1	0	1
		Anxiety	2	0	1
		Confusional state	1	0	1
		Depression	2	0	1

7 Outcome Description

(Causality possible, Causality probable, Causality certain)

Suspect Type

Y Suspect Code

T Case Group

₮ <u>GM</u>

			Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Hallucination	2	0	0
		Thinking abnormal	1	0	1
		Anger	1	0	1
		Elevated mood	1	0	0
		Listless	2	0	2
		Abnormal behaviour	1	0	0
		Mental disorder	1	0	1
		Psychotic disorder	1	0	0
		Insomnia	1	0	1
		Suicidal ideation	2	0	1
		Suicide attempt	2	0	0
		Psychiatric disorders	21	0	11
	Renal and urinary disorders	Nephrotic syndrome	1	0	0
		Renal failure acute	2	0	1
		Renal tubular necrosis	1	0	0
		Urinary retention	1	0	0
		Albuminuria	1	0	0
		Renal and urinary disorders	6	0	1
	Reproductive system and breast disorders	Breast enlargement	3	0	3
		Sexual dysfunction	1	0	1
		Reproductive system and breast disorders	4	0	4
	Respiratory, thoracic and mediastinal disorders	Wheezing	3	0	3
		Eosinophilic pneumonia	1	0	1
		Pulmonary embolism	1	1	0
		Dyspnoea	5	0	4
		Hypoventilation	1	0	0
		Cough	1	0	0
		Respiratory failure	1	0	0
		Respiratory, thoracic and mediastinal disorders	13	1	8
	Skin and subcutaneous tissue disorders	Angioedema	1	0	1
		Urticaria	5	0	5
		Swelling face	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	Skin and subcutaneous tissue disorders	Rash erythematous	5	0	4
Count		Pruritus	7	0	6
		Rash	3	0	1
		Rash generalised	1	0	0
		Rash maculo-papular	2	0	1
		Skin ulcer	1	0	1
		Acne	1	0	1
		Hyperhidrosis	1	0	0
		Skin and subcutaneous tissue disorders	29	0	22
	Social circumstances	Treatment noncompliance	1	0	0
		Life expectancy shortened	1	0	1
		Social circumstances	2	0	1
	Vascular disorders	Circulatory collapse	1	0	0
		Hypotension	1	0	1
		Deep vein thrombosis	2	1	0
		Hypertension	2	0	1
		Vascular disorders	6	1	2
	Reaction		266	5	175

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

7 Outcome Description

(Causality possible, Causality probable, Causality certain)

Suspect Type

Suspect Code

T Case Group

₹ <u>GM</u>