

Summary Tabulation 26-01-2021

Active Substance (High Level)		COVID-19 MRNA VACCINE PFIZER-BIONTECH (TOZINAMERAN)		
Reaction SOC	Reaction PT	Serious	Non Serious	Total
Blood and lymphatic system disorders	Coagulopathy	1	1	2
	Leukocytosis	1	0	1
	Lymph node pain	1	0	1
	Lymphadenitis	0	1	1
	Lymphadenopathy	1	1	2
	Neutropenia	1	0	1
Cardiac disorders	Bradycardia	1	0	1
	Cardiac failure	1	0	1
	Cardio-respiratory arrest	1	0	1
	Cardiovascular disorder	5	2	7
	Palpitations	0	1	1
	Tachycardia	1	0	1
Ear and labyrinth disorders	Ear pain	0	1	1
	Vertigo	2	0	2
Eye disorders	Asthenopia	0	2	2
	Eye movement disorder	1	0	1
	Mydriasis	0	1	1
	Visual impairment	0	1	1
Gastrointestinal disorders	Abdominal discomfort	0	1	1
	Abdominal pain	1	0	1
	Abdominal pain upper	0	2	2
	Anal incontinence	0	1	1
	Diarrhoea	0	1	1
	Glossodynia	0	1	1
	Intestinal dilatation	1	0	1
	Intestinal ischaemia	2	0	2
	Lip swelling	0	1	1
	Nausea	6	20	26
	Paraesthesia oral	0	1	1
	Rectal haemorrhage	1	0	1
	Swollen tongue	0	1	1
	Vomiting	0	3	3
General disorders and administration site conditions	Axillary pain	0	1	1
	Chest pain	2	0	2
	Chills	10	23	33

	Death	3	0	3
	Face oedema	1	1	2
	Facial pain	0	1	1
	Fatigue	8	37	45
	Feeling cold	0	1	1
	Feeling hot	0	3	3
	Feeling of body temperature change	0	2	2
	Gait inability	0	2	2
	General physical health deterioration	1	0	1
	Hyperthermia	0	1	1
	Influenza like illness	0	4	4
	Injection site bruising	0	1	1
	Injection site discomfort	0	1	1
	Injection site erythema	1	19	20
	Injection site haematoma	0	3	3
	Injection site induration	0	5	5
	Injection site movement impairment	0	1	1
	Injection site pain	1	15	16
	Injection site pruritus	0	1	1
	Injection site reaction	2	7	9
	Injection site swelling	1	9	10
	Injection site warmth	0	3	3
	Malaise	7	17	24
	Pain	0	3	3
	Peripheral swelling	0	4	4
	Pyrexia	7	42	49
	Sense of oppression	0	1	1
	Sudden death	3	0	3
	Swelling face	0	1	1
	Thirst	0	1	1
	Vaccination site erythema	0	1	1
	Vaccination site pain	0	1	1
	Vaccination site pruritus	0	1	1
	Vaccination site swelling	0	1	1
Immune system disorders	Anaphylactic reaction	2	0	2
Infections and infestations	COVID-19	1	1	2
	Influenza	0	1	1
	Pharyngitis	0	1	1
	Sepsis	1	0	1
	Septic shock	1	0	1
	Sinusitis	0	1	1
	Tonsillitis	0	1	1
Injury, poisoning and procedural complications	Contusion	0	1	1
Investigations	Blood glucose fluctuation	0	1	1
	Blood lactic acid increased	2	0	2
	Blood pressure decreased	0	1	1
	Blood pressure increased	1	1	2
	Body temperature increased	0	4	4

	Haemoglobin decreased	1	0	1
	Heart rate irregular	0	1	1
	Liver function test abnormal	1	0	1
	Oxygen saturation decreased	2	0	2
Metabolism and nutrition disorders	Decreased appetite	0	4	4
	Diabetic complication	1	0	1
	Hypoglycaemia	1	0	1
	Metabolic acidosis	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	2	6	8
	Jaw disorder	0	1	1
	Musculoskeletal chest pain	0	2	2
	Musculoskeletal stiffness	0	7	7
	Myalgia	6	36	42
	Neck pain	1	1	2
	Pain in extremity	1	29	30
	Posture abnormal	0	1	1
Nervous system disorders	Amnesia	1	0	1
	Depressed level of consciousness	1	0	1
	Dizziness	0	5	5
	Dysgeusia	0	3	3
	Epilepsy	1	0	1
	Facial paresis	1	0	1
	Facial spasm	0	2	2
	Haemorrhage intracranial	1	0	1
	Headache	7	38	45
	Hypoaesthesia	1	2	3
	Migraine	0	1	1
	Nervous system disorder	1	3	4
	Paraesthesia	0	8	8
	Parosmia	0	1	1
	Patient elopement	1	0	1
	Presyncope	2	4	6
	Speech disorder	0	1	1
	Syncope	1	0	1
Psychiatric disorders	Agitation	3	2	5
	Anxiety	0	1	1
	Confusional state	2	4	6
	Disorientation	1	0	1
	Staring	1	0	1
Renal and urinary disorders	Acute kidney injury	1	0	1
	Renal disorder	1	0	1
	Renal failure	1	0	1
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	1	0	1
	Bronchospasm	1	0	1
	Cough	0	3	3
	Dyspnoea	1	1	2
	Laryngeal discomfort	0	1	1
	Lung infiltration	1	0	1
	Nasal congestion	0	1	1
	Oropharyngeal pain	0	3	3

	Pharyngeal swelling	0	1	1
	Pneumonitis	1	0	1
	Pulmonary embolism	1	0	1
	Respiratory disorder	4	6	10
	Rhinorrhoea	0	2	2
	Sneezing	0	1	1
	Tachypnoea	1	0	1
	Upper airway obstruction	1	0	1
Skin and subcutaneous tissue disorders	Erythema	1	7	8
	Hyperhidrosis	1	1	2
	Pruritus	0	5	5
	Rash	1	3	4
	Rash erythematous	0	3	3
	Skin disorder	0	3	3
	Urticaria	1	2	3
Vascular disorders	Haematoma	0	1	1
	Hot flush	1	1	2
	Hypertension	1	2	3
	Hypotension	1	1	2
	Hypovolaemic shock	2	0	2
	Neurogenic shock	1	0	1
Total		150	481	631