

Summary Tabulation 02-02-2021

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	1	2
	Lymphadenitis	0	1	1
	Lymphadenopathy	1	2	3
	Neutropenia	1	0	1
Cardiac disorders	Arrhythmia	1	0	1
	Atrial fibrillation	0	1	1
	Atrioventricular block complete	1	0	1
	Bradycardia	1	0	1
	Cardiac arrest	1	0	1
	Cardiac failure	2	0	2
	Cardio-respiratory arrest	1	0	1
	Cardiovascular disorder	7	4	11
	Palpitations	1	6	7
	Stress cardiomyopathy	0	1	1
	Tachycardia	2	1	3
Ear and labyrinth disorders	Deafness unilateral	1	0	1
	Ear pain	0	2	2
	Endolymphatic hydrops	1	0	1
	Vertigo	3	5	8
Eye disorders	Abnormal sensation in eye	0	1	1
	Asthenopia	0	2	2
	Eye movement disorder	1	0	1
	Eye swelling	0	1	1
	Glaucoma	1	0	1
	Mydriasis	0	1	1
	Ocular hyperaemia	1	0	1
	Vision blurred	0	2	2
Visual impairment	0	1	1	
Gastrointestinal disorders	Abdominal discomfort	0	2	2
	Abdominal pain	1	0	1
	Abdominal pain upper	0	2	2
	Anal incontinence	0	1	1
	Diarrhoea	0	4	4
	Dry mouth	1	0	1
	Dyspepsia	0	1	1

Dysphagia	1	1	2
Glossodynia	0	1	1
Hypoaesthesia oral	0	1	1
Intestinal dilatation	1	0	1
Intestinal ischaemia	2	0	2
Lip swelling	1	1	2
Nausea	14	38	52
Paraesthesia oral	0	2	2
Rectal haemorrhage	1	0	1
Salivary hypersecretion	1	1	2
Swollen tongue	0	2	2
Vomiting	0	7	7
General disorders and administration site conditions			
Asthenia	1	3	4
Axillary pain	0	1	1
Chest pain	3	1	4
Chills	18	41	59
Death	3	0	3
Drug ineffective	1	0	1
Face oedema	1	1	2
Facial pain	0	1	1
Fatigue	21	74	95
Feeling cold	0	1	1
Feeling hot	0	5	5
Feeling of body temperature change	0	6	6
Gait inability	0	2	2
General physical health deterioration	3	0	3
Hyperthermia	0	2	2
Illness	1	0	1
Influenza like illness	0	6	6
Injection site bruising	0	1	1
Injection site discomfort	0	1	1
Injection site erythema	1	25	26
Injection site haematoma	0	3	3
Injection site hypoaesthesia	0	1	1
Injection site induration	0	11	11
Injection site movement impairment	0	1	1
Injection site pain	2	37	39
Injection site pruritus	0	1	1
Injection site reaction	6	41	47
Injection site swelling	1	11	12
Injection site warmth	0	4	4
Malaise	18	40	58
Pain	0	5	5
Peripheral swelling	2	14	16
Pyrexia	17	74	91
Sensation of foreign body	1	1	2
Sense of oppression	0	2	2
Sudden death	5	0	5
Swelling	1	1	2
Swelling face	0	1	1

	Thirst	0	1	1
	Vaccination site erythema	0	2	2
	Vaccination site pain	0	2	2
	Vaccination site pruritus	0	1	1
	Vaccination site swelling	0	1	1
	Vaccination site warmth	0	1	1
Immune system disorders	Anaphylactic reaction	6	1	7
	Hypersensitivity	0	1	1
Infections and infestations	COVID-19	3	3	6
	COVID-19 pneumonia	1	0	1
	Herpes ophthalmic	1	0	1
	Herpes zoster	0	2	2
	Influenza	0	2	2
	Oral herpes	1	0	1
	Pharyngitis	0	1	1
	Pneumonia	2	0	2
	Rhinitis	0	1	1
	Sepsis	2	0	2
	Septic shock	1	0	1
	Sinusitis	0	1	1
	Tonsillitis	0	1	1
Injury, poisoning and procedural complications	Contusion	0	1	1
	Incorrect dose administered	0	1	1
Investigations	Blood creatine phosphokinase increased	0	1	1
	Blood glucose fluctuation	0	1	1
	Blood lactic acid increased	2	0	2
	Blood pressure decreased	1	3	4
	Blood pressure increased	1	1	2
	Body temperature increased	1	4	5
	Haemoglobin decreased	1	0	1
	Heart rate irregular	0	1	1
	Liver function test abnormal	1	0	1
	Oxygen saturation decreased	7	0	7
Metabolism and nutrition disorders	Decreased appetite	0	5	5
	Diabetic complication	1	0	1
	Hypoglycaemia	1	1	2
	Metabolic acidosis	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	6	12	18
	Bone pain	0	1	1
	Jaw disorder	0	1	1
	Joint stiffness	1	0	1
	Muscle spasms	0	2	2
	Muscular weakness	0	2	2
	Musculoskeletal chest pain	0	2	2
	Musculoskeletal stiffness	1	14	15
	Myalgia	16	59	75
	Neck pain	1	1	2
	Pain in extremity	1	34	35
	Posture abnormal	0	1	1
Nervous system disorders	Ageusia	0	1	1

	Amnesia	1	0	1
	Balance disorder	2	0	2
	Burning sensation	0	1	1
	Depressed level of consciousness	1	0	1
	Disturbance in attention	0	1	1
	Dizziness	2	12	14
	Dysgeusia	0	6	6
	Dystonia	1	0	1
	Epilepsy	1	0	1
	Facial paresis	1	0	1
	Facial spasm	0	2	2
	Haemorrhage intracranial	1	0	1
	Headache	19	72	91
	Hypoaesthesia	1	3	4
	Memory impairment	0	1	1
	Migraine	0	1	1
	Nervous system disorder	4	4	8
	Neuropathy peripheral	1	0	1
	Paraesthesia	1	9	10
	Parosmia	0	1	1
	Patient elopement	1	0	1
	Poor quality sleep	0	1	1
	Presyncope	3	5	8
	Sedation	1	0	1
	Sensory disturbance	1	1	2
	Sleep deficit	1	0	1
	Somnolence	0	1	1
	Speech disorder	0	1	1
	Syncope	2	0	2
Psychiatric disorders	Agitation	3	2	5
	Anxiety	1	2	3
	Confusional state	2	5	7
	Depressed mood	0	1	1
	Disorientation	1	0	1
	Insomnia	1	1	2
	Staring	1	0	1
Renal and urinary disorders	Acute kidney injury	2	0	2
	Polyuria	0	1	1
	Renal disorder	1	0	1
	Renal failure	1	0	1
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	2	0	2
	Asthma exercise induced	1	0	1
	Bronchospasm	2	0	2
	Cough	0	3	3
	Dyspnoea	2	1	3
	Hyperventilation	1	0	1
	Hypoxia	1	0	1
	Laryngeal discomfort	0	1	1
	Laryngospasm	1	0	1
	Lung infiltration	1	0	1

	Nasal congestion	0	1	1
	Nasal discomfort	0	1	1
	Oropharyngeal pain	1	5	6
	Pharyngeal swelling	0	1	1
	Pneumonitis	1	0	1
	Pulmonary embolism	1	0	1
	Pulmonary oedema	1	0	1
	Respiratory disorder	7	8	15
	Respiratory distress	1	0	1
	Rhinorrhoea	1	3	4
	Sneezing	1	1	2
	Tachypnoea	1	0	1
	Upper airway obstruction	1	0	1
Skin and subcutaneous tissue disorders	Angioedema	1	1	2
	Dry skin	1	0	1
	Erythema	1	11	12
	Hyperhidrosis	1	1	2
	Pruritus	1	10	11
	Rash	1	5	6
	Rash erythematous	0	3	3
	Rash papular	0	1	1
	Skin disorder	2	7	9
	Skin reaction	0	1	1
	Urticaria	1	2	3
Vascular disorders	Flushing	0	1	1
	Haematoma	0	2	2
	Hot flush	1	2	3
	Hypertension	1	4	5
	Hypotension	2	3	5
	Hypovolaemic shock	2	0	2
	Lymphoedema	1	0	1
	Neurogenic shock	1	0	1
	Pallor	0	1	1
	Peripheral coldness	1	0	1
Total		322	900	1 222