

## Summary Tabulation 09-02-2021

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	4	5
	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	2	0	2
	Cardiovascular disorder	7	5	12
	Palpitations	1	8	9
	Sinus tachycardia	1	0	1
	Stress cardiomyopathy	0	1	1
	Tachycardia	5	2	7
Ear and labyrinth disorders	Deafness unilateral	1	0	1
	Ear pain	1	2	3
	Endolymphatic hydrops	1	0	1
	Hypoacusis	0	1	1
	Tinnitus	0	1	1
	Vertigo	5	5	10
	Vertigo positional	0	1	1
Eye disorders	Abnormal sensation in eye	0	1	1
	Asthenopia	0	2	2
	Eye movement disorder	1	0	1
	Eye swelling	1	1	2
	Glaucoma	1	0	1
	Mydriasis	0	1	1
	Ocular hyperaemia	1	0	1
	Vision blurred	1	2	3
	Visual impairment	0	1	1
Gastrointestinal disorders	Abdominal discomfort	0	2	2

	Abdominal pain	2	1	3
	Abdominal pain upper	2	2	4
	Anal incontinence	0	1	1
	Diarrhoea	0	8	8
	Dry mouth	1	0	1
	Dyspepsia	0	1	1
	Dysphagia	1	2	3
	Gastrooesophageal reflux disease	0	1	1
	Glossodynia	0	1	1
	Hypoesthesia oral	0	1	1
	Intestinal dilatation	1	0	1
	Intestinal ischaemia	2	0	2
	Lip swelling	1	2	3
	Nausea	26	60	86
	Paraesthesia oral	0	2	2
	Rectal haemorrhage	1	0	1
	Salivary hypersecretion	1	1	2
	Swollen tongue	1	2	3
	Tongue discolouration	0	1	1
	Vomiting	3	11	14
General disorders and administration site conditions	Asthenia	1	3	4
	Axillary pain	0	2	2
	Chest discomfort	1	0	1
	Chest pain	3	1	4
	Chills	27	68	95
	Death	3	0	3
	Drug ineffective	1	0	1
	Face oedema	1	1	2
	Facial pain	0	1	1
	Fatigue	33	106	139
	Feeling cold	0	1	1
	Feeling hot	0	5	5
	Feeling of body temperature change	1	6	7
	Gait disturbance	1	0	1
	Gait inability	0	3	3
	General physical health deterioration	4	0	4
	Hyperthermia	0	5	5
	Illness	1	0	1
	Inflammation	0	2	2
	Influenza like illness	2	6	8
	Injection site bruising	0	1	1
	Injection site discomfort	0	1	1
	Injection site erythema	1	33	34
	Injection site haematoma	0	4	4
	Injection site haemorrhage	0	1	1
	Injection site hypoesthesia	0	1	1
	Injection site induration	0	14	14
	Injection site movement impairment	0	1	1
	Injection site oedema	0	1	1
	Injection site pain	3	45	48

	Injection site pruritus	0	2	2
	Injection site rash	0	1	1
	Injection site reaction	14	63	77
	Injection site swelling	1	14	15
	Injection site warmth	0	5	5
	Malaise	30	56	86
	Pain	1	5	6
	Peripheral swelling	6	27	33
	Pyrexia	27	108	135
	Sensation of foreign body	1	1	2
	Sense of oppression	0	2	2
	Sudden death	8	0	8
	Swelling	1	1	2
	Swelling face	0	2	2
	Thirst	0	1	1
	Vaccination site erythema	0	2	2
	Vaccination site pain	0	4	4
	Vaccination site pruritus	0	1	1
	Vaccination site swelling	0	1	1
	Vaccination site warmth	0	1	1
Immune system disorders	Anaphylactic reaction	10	2	12
	Hypersensitivity	0	1	1
Infections and infestations	COVID-19	4	5	9
	COVID-19 pneumonia	1	0	1
	Erysipelas	1	0	1
	Herpes ophthalmic	2	0	2
	Herpes zoster	0	4	4
	Influenza	0	6	6
	Laryngitis	1	0	1
	Nasopharyngitis	0	1	1
	Oral herpes	2	0	2
	Pharyngitis	0	1	1
	Pneumonia	2	0	2
	Rhinitis	0	2	2
	Rhinolaryngitis	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	Chillblains	1	0	1
	Contusion	0	1	1
	Fall	2	0	2
	Incorrect dose administered	0	1	1
Investigations	Blood creatine phosphokinase increased	0	1	1
	Blood glucose fluctuation	0	1	1
	Blood lactic acid increased	3	0	3
	Blood pressure decreased	2	4	6
	Blood pressure increased	1	1	2
	Body temperature increased	1	5	6
	Haemoglobin decreased	1	0	1

	Heart rate increased	1	0	1
	Heart rate irregular	0	1	1
	Liver function test abnormal	2	0	2
	Oxygen saturation decreased	7	2	9
	Respiratory rate increased	1	0	1
	SARS-CoV-2 test positive	1	0	1
	Troponin increased	1	0	1
Metabolism and nutrition disorders	Decreased appetite	0	5	5
	Diabetic complication	1	0	1
	Hypoglycaemia	2	1	3
	Metabolic acidosis	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	13	25	38
	Arthritis	1	0	1
	Bone pain	0	1	1
	Groin pain	0	1	1
	Jaw disorder	0	1	1
	Joint stiffness	1	0	1
	Muscle spasms	0	2	2
	Muscular weakness	0	3	3
	Musculoskeletal chest pain	0	2	2
	Musculoskeletal discomfort	0	1	1
	Musculoskeletal stiffness	2	20	22
	Myalgia	30	93	123
	Neck pain	3	1	4
	Pain in extremity	4	35	39
	Posture abnormal	0	1	1
Nervous system disorders	Ageusia	0	3	3
	Altered state of consciousness	1	0	1
	Amnesia	1	0	1
	Anosmia	0	1	1
	Balance disorder	2	0	2
	Burning sensation	1	2	3
	Depressed level of consciousness	4	0	4
	Disturbance in attention	0	1	1
	Dizziness	4	13	17
	Dysgeusia	1	7	8
	Dystonia	1	0	1
	Epilepsy	2	0	2
	Facial paresis	1	0	1
	Facial spasm	0	2	2
	Generalised tonic-clonic seizure	1	0	1
	Haemorrhage intracranial	1	0	1
	Headache	37	113	150
	Hemiplegia	1	0	1
	Hypoesthesia	1	3	4
	Memory impairment	1	0	1
	Migraine	0	2	2
	Nervous system disorder	6	7	13
	Neuropathy peripheral	1	0	1
	Paraesthesia	2	10	12

	Parosmia	0	1	1
	Patient elopement	1	0	1
	Poor quality sleep	0	1	1
	Presyncope	3	8	11
	Sedation	2	0	2
	Sensory disturbance	1	1	2
	Sleep deficit	1	0	1
	Somnolence	1	1	2
	Speech disorder	0	1	1
	Syncope	10	0	10
	Thoracic outlet syndrome	1	0	1
	Tremor	1	0	1
Psychiatric disorders	Agitation	3	2	5
	Anxiety	2	2	4
	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	2	0	2
Reproductive system and breast disorders	Pelvic pain	0	1	1
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	2	0	2
	Asthma exercise induced	1	0	1
	Bronchospasm	3	0	3
	Cough	1	5	6
	Dry throat	1	0	1
	Dysphonia	1	1	2
	Dyspnoea	6	2	8
	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	7	8
	Pharyngeal swelling	1	1	2
	Pleural effusion	1	0	1
	Pneumonitis	1	0	1
	Productive cough	0	1	1
	Pulmonary embolism	1	0	1
	Pulmonary oedema	1	0	1
	Respiration abnormal	1	0	1
	Respiratory disorder	8	10	18
	Respiratory distress	1	0	1
	Rhinorrhoea	1	4	5
	Sneezing	1	1	2

	Tachypnoea	2	0	2
	Upper airway obstruction	1	0	1
	Wheezing	1	0	1
Skin and subcutaneous tissue disorders	Angioedema	2	1	3
	Dermatitis	0	1	1
	Dry skin	1	0	1
	Erythema	1	15	16
	Hyperhidrosis	1	1	2
	Livedo reticularis	1	0	1
	Pruritus	2	12	14
	Rash	1	5	6
	Rash erythematous	1	5	6
	Rash papular	0	1	1
	Skin disorder	3	9	12
	Skin reaction	0	1	1
	Urticaria	2	3	5
	Vascular disorders	Cyanosis	1	0
Flushing		0	2	2
Haematoma		1	2	3
Hot flush		3	4	7
Hypertension		3	4	7
Hypotension		5	4	9
Hypovolaemic shock		2	0	2
Lymphoedema		1	0	1
Neurogenic shock		2	0	2
Pallor		1	1	2
Peripheral coldness		1	1	2
<b>Total</b>			<b>543</b>	<b>1281</b>

Rows 1 - 263 (All Rows)