

Summary Tabulation 02-03-2021

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	3	3	6
	Leukocytosis	1	0	1
	Lymph node pain	1	2	3
	Lymphadenitis	0	1	1
	Lymphadenopathy	3	13	16
	Neutropenia	1	0	1
	Thrombocytopenia	3	0	3
Cardiac disorders	Angina pectoris	1	1	2
	Arrhythmia	2	0	2
	Atrial fibrillation	3	0	3
	Atrioventricular block	1	0	1
	Atrioventricular block complete	1	0	1
	Bradycardia	4	0	4
	Cardiac arrest	3	0	3
	Cardiac disorder	1	0	1
	Cardiac failure	2	0	2
	Cardio-respiratory arrest	3	0	3
	Cardiovascular disorder	19	13	32
	Palpitations	3	8	11
	Pericardial effusion	1	0	1
	Rhythm idioventricular	1	0	1
	Sinus tachycardia	1	0	1
	Stress cardiomyopathy	0	1	1
	Tachyarrhythmia	1	0	1
	Tachycardia	11	14	25
Ear and labyrinth disorders	Deafness unilateral	1	0	1
	Ear pain	1	3	4
	Endolymphatic hydrops	2	0	2
	Hypoacusis	1	1	2
	Sudden hearing loss	1	0	1
	Tinnitus	2	1	3
	Vertigo	12	7	19
	Vertigo positional	0	1	1
Endocrine disorders	Goitre	0	1	1
Eye disorders	Abnormal sensation in eye	0	1	1

	Asthenopia	0	2	2
	Diplopia	1	0	1
	Eye movement disorder	1	0	1
	Eye pain	0	1	1
	Eye swelling	2	1	3
	Glaucoma	1	0	1
	Mydriasis	0	1	1
	Ocular hyperaemia	1	0	1
	Photopsia	1	1	2
	Swelling of eyelid	1	0	1
	Vision blurred	2	2	4
	Visual impairment	2	2	4
	Vitreous floaters	0	1	1
Gastrointestinal disorders	Abdominal discomfort	0	2	2
	Abdominal pain	3	8	11
	Abdominal pain upper	2	3	5
	Anal incontinence	0	1	1
	Aphthous ulcer	0	1	1
	Constipation	0	1	1
	Diarrhoea	4	22	26
	Dry mouth	1	1	2
	Dyspepsia	0	2	2
	Dysphagia	2	1	3
	Faeces discoloured	1	0	1
	Gastrointestinal pain	0	1	1
	Gastrooesophageal reflux disease	0	1	1
	Glossodynia	0	1	1
	Hypoaesthesia oral	0	1	1
	Intestinal dilatation	1	0	1
	Intestinal ischaemia	2	0	2
	Lip swelling	3	1	4
	Nausea	95	149	244
	Oral pruritus	0	1	1
	Paraesthesia oral	1	5	6
	Parotid gland enlargement	0	1	1
	Rectal haemorrhage	1	0	1
	Retching	2	0	2
	Salivary hypersecretion	2	0	2
	Stomatitis	0	1	1
	Swollen tongue	2	4	6
	Tongue discolouration	0	1	1
	Tongue discomfort	0	1	1
	Vomiting	11	22	33
General disorders and administration site conditions	Asthenia	8	16	24
	Axillary pain	0	7	7
	Chest discomfort	8	0	8
	Chest pain	7	2	9
	Chills	109	159	268
	Death	3	0	3
	Drug ineffective	1	0	1

Exercise tolerance decreased	4	0	4
Face oedema	1	2	3
Facial pain	0	1	1
Fatigue	129	258	387
Feeling abnormal	2	0	2
Feeling cold	2	3	5
Feeling drunk	0	1	1
Feeling hot	0	7	7
Feeling of body temperature change	1	8	9
Gait disturbance	1	0	1
Gait inability	0	3	3
General physical health deterioration	11	0	11
Hyperthermia	0	6	6
Hypothermia	1	1	2
Illness	1	0	1
Inflammation	0	3	3
Influenza like illness	16	21	37
Injection site bruising	0	1	1
Injection site discomfort	0	2	2
Injection site erythema	4	56	60
Injection site haematoma	0	7	7
Injection site haemorrhage	0	1	1
Injection site hypoaesthesia	0	1	1
Injection site induration	1	24	25
Injection site inflammation	0	1	1
Injection site movement impairment	1	1	2
Injection site oedema	0	1	1
Injection site pain	14	101	115
Injection site paraesthesia	0	1	1
Injection site pruritus	0	3	3
Injection site rash	0	3	3
Injection site reaction	54	123	177
Injection site swelling	5	23	28
Injection site warmth	1	13	14
Malaise	88	142	230
Oedema	0	1	1
Pain	2	6	8
Peripheral swelling	12	46	58
Pyrexia	112	224	336
Secretion discharge	0	1	1
Sensation of foreign body	2	0	2
Sense of oppression	1	8	9
Sudden death	12	0	12
Swelling	1	6	7
Swelling face	2	2	4
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	1	1	2

	Vaccination site warmth	0	1	1
Immune system disorders	Anaphylactic reaction	14	1	15
	Anaphylactic shock	2	0	2
	Anaphylactoid reaction	1	0	1
	Autoimmune disorder	0	1	1
	Hypersensitivity	2	7	9
Infections and infestations	Appendicitis	1	0	1
	COVID-19	10	12	22
	COVID-19 pneumonia	1	0	1
	Ear infection	0	1	1
	Erysipelas	1	0	1
	Herpes ophthalmic	2	0	2
	Herpes simplex	1	0	1
	Herpes virus infection	0	1	1
	Herpes zoster	1	7	8
	Influenza	1	8	9
	Laryngitis	1	0	1
	Localised infection	1	0	1
	Nasopharyngitis	0	2	2
	Oral herpes	3	0	3
	Parapharyngeal space infection	1	0	1
	Pharyngitis	0	2	2
	Pneumonia	3	0	3
	Pneumonia bacterial	1	0	1
	Respiratory tract infection	2	0	2
	Rhinitis	0	2	2
	Rhinolaryngitis	0	1	1
	Sepsis	2	0	2
	Septic shock	1	0	1
	Sinusitis	0	2	2
Tonsillitis	0	1	1	
Injury, poisoning and procedural complications	Chillblains	1	0	1
	Contusion	0	1	1
	Drug administered in wrong device	0	1	1
	Fall	7	0	7
	Incorrect dose administered	0	1	1
	Incorrect route of product administration	0	1	1
Investigations	Blood creatine phosphokinase increased	0	1	1
	Blood glucose decreased	0	1	1
	Blood glucose fluctuation	0	1	1
	Blood lactic acid increased	3	0	3
	Blood pressure abnormal	1	0	1
	Blood pressure decreased	4	3	7
	Blood pressure increased	3	2	5
	Body temperature fluctuation	1	0	1
	Body temperature increased	4	7	11
	Fibrin D dimer increased	1	0	1
	Haemoglobin decreased	1	0	1
	Heart rate decreased	1	0	1
	Heart rate increased	3	0	3

	Heart rate irregular	0	1	1
	Liver function test abnormal	3	0	3
	Oxygen saturation decreased	20	3	23
	Respiratory rate increased	1	0	1
	SARS-CoV-2 test positive	2	0	2
	Troponin increased	2	0	2
	Weight decreased	1	0	1
Metabolism and nutrition disorders	Decreased appetite	2	9	11
	Dehydration	1	0	1
	Diabetic complication	1	0	1
	Hypoglycaemia	2	2	4
	Metabolic acidosis	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	53	72	125
	Arthritis	2	1	3
	Back pain	3	3	6
	Bone pain	1	1	2
	Groin pain	0	1	1
	Jaw disorder	0	1	1
	Joint stiffness	1	0	1
	Muscle spasms	1	2	3
	Muscular weakness	2	6	8
	Musculoskeletal chest pain	0	2	2
	Musculoskeletal discomfort	0	1	1
	Musculoskeletal stiffness	6	26	32
	Myalgia	112	238	350
	Neck pain	4	8	12
	Pain in extremity	10	52	62
	Pain in jaw	1	0	1
	Posture abnormal	0	1	1
Nervous system disorders	Ageusia	0	3	3
	Allodynia	1	0	1
	Altered state of consciousness	3	2	5
	Amnesia	1	0	1
	Anosmia	0	3	3
	Aphasia	1	0	1
	Balance disorder	4	1	5
	Burning sensation	1	4	5
	Cerebrovascular accident	4	0	4
	Coma	2	0	2
	Depressed level of consciousness	10	0	10
	Disturbance in attention	0	2	2
	Dizziness	14	16	30
	Dysaesthesia	1	0	1
	Dysgeusia	5	9	14
	Dysstasia	1	0	1
	Dystonia	1	0	1
	Epilepsy	7	0	7
	Facial paralysis	2	0	2
	Facial paresis	4	0	4
	Facial spasm	0	2	2

Formication	1	0	1
Generalised tonic-clonic seizure	1	0	1
Haemorrhage intracranial	1	0	1
Head discomfort	1	1	2
Headache	136	264	400
Hemiplegia	2	0	2
Hypersomnia	1	0	1
Hypoaesthesia	2	8	10
Lethargy	1	0	1
Loss of consciousness	1	0	1
Memory impairment	1	0	1
Migraine	5	5	10
Migraine with aura	1	0	1
Nervous system disorder	15	20	35
Neuralgia	1	0	1
Neuritis	1	0	1
Neuropathy peripheral	1	0	1
Paraesthesia	3	15	18
Parkinson's disease	2	0	2
Parosmia	0	1	1
Patient elopement	1	0	1
Poor quality sleep	0	1	1
Presyncope	5	13	18
Sedation	3	0	3
Seizure	4	0	4
Sensory disturbance	1	1	2
Sleep deficit	1	0	1
Somnolence	2	2	4
Speech disorder	0	2	2
Syncope	13	0	13
Taste disorder	0	1	1
Thoracic outlet syndrome	1	0	1
Tremor	4	2	6
Unresponsive to stimuli	3	0	3
Visual field defect	1	0	1
Psychiatric disorders			
Agitation	4	2	6
Anxiety	6	2	8
Apathy	1	1	2
Confusional state	3	8	11
Depressed mood	0	1	1
Disorientation	1	0	1
Hallucination	2	0	2
Insomnia	4	2	6
Irritability	1	0	1
Restlessness	1	1	2
Staring	1	0	1
Renal and urinary disorders			
Acute kidney injury	2	0	2
Polyuria	0	1	1
Renal disorder	2	0	2
Renal failure	2	0	2

	Renal pain	2	1	3
	Urinary retention	1	0	1
Reproductive system and breast disorders	Pelvic pain	0	1	1
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1
	Acute respiratory failure	2	0	2
	Asthma	0	1	1
	Asthma exercise induced	1	0	1
	Bronchial disorder	1	0	1
	Bronchospasm	3	0	3
	Cheyne-Stokes respiration	1	0	1
	Cough	6	8	14
	Dry throat	1	0	1
	Dysphonia	1	1	2
	Dyspnoea	23	5	28
	Epistaxis	0	4	4
	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	5	11	16
	Painful respiration	0	1	1
	Pharyngeal swelling	2	2	4
	Pleural effusion	2	0	2
	Pneumonia aspiration	1	0	1
	Pneumonitis	1	0	1
	Productive cough	0	1	1
	Pulmonary embolism	5	0	5
	Pulmonary infarction	1	0	1
	Pulmonary oedema	2	0	2
	Rales	1	0	1
	Respiration abnormal	2	0	2
	Respiratory disorder	23	23	46
	Respiratory distress	1	0	1
	Respiratory failure	1	0	1
	Rhinorrhoea	3	4	7
	Sinus pain	1	0	1
	Sneezing	1	1	2
	Tachypnoea	2	0	2
	Upper airway obstruction	1	0	1
	Wheezing	1	0	1
Skin and subcutaneous tissue disorders	Angioedema	3	0	3
	Cold sweat	1	0	1
	Dermatitis	0	1	1
	Dry skin	1	0	1
	Eczema	0	1	1
	Erythema	8	15	23
	Hyperhidrosis	4	6	10

	Livedo reticularis	1	0	1
	Night sweats	1	0	1
	Pain of skin	1	0	1
	Pruritus	6	16	22
	Rash	4	10	14
	Rash erythematous	1	8	9
	Rash macular	1	0	1
	Rash papular	0	1	1
	Rash pruritic	1	0	1
	Sensitive skin	1	0	1
	Skin burning sensation	1	0	1
	Skin disorder	12	16	28
	Skin reaction	0	1	1
	Urticaria	3	6	9
	Urticaria papular	0	1	1
	Yellow skin	1	0	1
Vascular disorders	Cyanosis	1	1	2
	Flushing	1	1	2
	Haematoma	2	4	6
	Hot flush	5	11	16
	Hypertension	10	9	19
	Hypotension	7	7	14
	Hypovolaemic shock	2	0	2
	Lymphoedema	1	0	1
	Neurogenic shock	2	0	2
	Pallor	3	1	4
	Peripheral coldness	2	1	3
	Thrombophlebitis	1	0	1
	Thrombosis	1	0	1
	Vasculitis	0	1	1
Total		1667	2698	4 365