

Summary Tabulation 16.02.2021

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	2	3	5
	Leukocytosis	1	0	1
	Lymph node pain	1	1	2
	Lymphadenitis	0	1	1
	Lymphadenopathy	1	8	9
	Neutropenia	1	0	1
	Thrombocytopenia	1	0	1
Cardiac disorders	Arrhythmia	1	0	1
	Atrial fibrillation	0	1	1
	Atrioventricular block complete	1	0	1
	Bradycardia	1	1	2
	Cardiac arrest	1	0	1
	Cardiac disorder	1	0	1
	Cardiac failure	2	0	2
	Cardio-respiratory arrest	3	0	3
	Cardiovascular disorder	11	8	19
	Palpitations	1	9	10
	Sinus tachycardia	1	0	1
	Stress cardiomyopathy	0	1	1
	Tachycardia	5	11	16
	Ear and labyrinth disorders	Deafness unilateral	1	0
Ear pain		1	2	3
Endolymphatic hydrops		1	0	1
Hypoacusis		0	1	1
Tinnitus		1	1	2
Vertigo		8	5	13
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	1	1	2
	Glaucoma	1	0	1

	Mydriasis	0	1	1
	Ocular hyperaemia	1	0	1
	Photopsia	0	1	1
	Vision blurred	2	2	4
	Visual impairment	0	2	2
	Vitreous floaters	0	1	1
Gastrointestinal disorders	Abdominal discomfort	0	2	2
	Abdominal pain	2	3	5
	Abdominal pain upper	2	3	5
	Anal incontinence	0	1	1
	Aphthous ulcer	0	1	1
	Diarrhoea	1	16	17
	Dry mouth	1	1	2
	Dyspepsia	0	1	1
	Dysphagia	1	2	3
	Gastroesophageal 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	1	2	3
	Nausea	39	98	137
	Paraesthesia oral	1	4	5
	Parotid gland enlargement	0	1	1
	Rectal haemorrhage	1	0	1
	Salivary hypersecretion	1	1	2
	Stomatitis	0	1	1
	Swollen tongue	1	2	3
	Tongue discolouration	0	1	1
	Vomiting	5	16	21
General disorders and administration site conditions	Asthenia	1	6	7
	Axillary pain	0	4	4
	Chest discomfort	2	0	2
	Chest pain	4	2	6
	Chills	39	104	143
	Death	3	0	3
	Drug ineffective	1	0	1
	Face oedema	1	1	2
	Facial pain	0	1	1
	Fatigue	52	163	215
	Feeling abnormal	1	0	1
	Feeling cold	2	3	5
	Feeling hot	0	7	7
	Feeling of body temperature change	1	6	7
	Gait disturbance	1	0	1
	Gait inability	0	3	3
	General physical health deterioration	7	0	7
	Hyperthermia	0	5	5
	Illness	1	0	1
	Inflammation	0	3	3

Influenza like illness	3	10	13
Injection site bruising	0	1	1
Injection site discomfort	0	2	2
Injection site erythema	3	43	46
Injection site haematoma	0	6	6
Injection site haemorrhage	0	1	1
Injection site hypoaesthesia	0	1	1
Injection site induration	0	18	18
Injection site movement impairment	0	1	1
Injection site oedema	0	1	1
Injection site pain	4	70	74
Injection site paraesthesia	0	1	1
Injection site pruritus	0	2	2
Injection site rash	0	1	1
Injection site reaction	20	86	106
Injection site swelling	2	19	21
Injection site warmth	0	8	8
Malaise	41	94	135
Pain	1	5	6
Peripheral swelling	7	37	44
Pyrexia	41	151	192
Sensation of foreign body	1	1	2
Sense of oppression	0	3	3
Sudden death	10	0	10
Swelling	1	3	4
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	11	4	15
Anaphylactic shock	1	0	1
Hypersensitivity	0	1	1
Infections and infestations			
COVID-19	6	11	17
COVID-19 pneumonia	1	0	1
Erysipelas	1	0	1
Herpes ophthalmic	2	0	2
Herpes virus infection	0	1	1
Herpes zoster	0	5	5
Influenza	1	7	8
Laryngitis	1	0	1
Nasopharyngitis	0	1	1
Oral herpes	2	1	3
Parapharyngeal space infection	0	1	1
Pharyngitis	0	2	2
Pneumonia	2	0	2
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	1	1
	Tonsillitis	0	1	1
Injury, poisoning and procedural complications	Chillblains	1	0	1
	Contusion	0	1	1
	Fall	4	0	4
	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	2	3
	Body temperature increased	3	7	10
	Fibrin D dimer increased	1	0	1
	Haemoglobin decreased	1	0	1
	Heart rate increased	1	0	1
	Heart rate irregular	0	1	1
	Liver function test abnormal	3	0	3
	Oxygen saturation decreased	10	2	12
	Respiratory rate increased	1	0	1
	SARS-CoV-2 test positive	1	0	1
	Troponin increased	2	0	2
Metabolism and nutrition disorders	Decreased appetite	0	8	8
	Diabetic complication	1	0	1
	Hypoglycaemia	2	1	3
	Metabolic acidosis	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	18	42	60
	Arthritis	1	1	2
	Back pain	0	1	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	4	4
	Musculoskeletal chest pain	0	2	2
	Musculoskeletal discomfort	0	1	1
	Musculoskeletal stiffness	2	23	25
	Myalgia	48	156	204
	Neck pain	3	5	8
	Pain in extremity	5	42	47
	Posture abnormal	0	1	1
Nervous system disorders	Ageusia	0	3	3
	Altered state of consciousness	2	0	2
	Amnesia	1	0	1
	Anosmia	0	2	2
	Balance disorder	3	0	3
	Burning sensation	1	3	4

	Cerebrovascular accident	1	0	1
	Coma	1	0	1
	Depressed level of consciousness	7	0	7
	Disturbance in attention	0	1	1
	Dizziness	6	16	22
	Dysgeusia	2	9	11
	Dysstasia	1	0	1
	Dystonia	1	0	1
	Epilepsy	4	0	4
	Facial paresis	2	0	2
	Facial spasm	0	2	2
	Formication	1	0	1
	Generalised tonic-clonic seizure	1	0	1
	Haemorrhage intracranial	1	0	1
	Head discomfort	1	0	1
	Headache	55	177	232
	Hemiplegia	1	0	1
	Hypoaesthesia	1	7	8
	Memory impairment	1	0	1
	Migraine	1	3	4
	Nervous system disorder	10	10	20
	Neuropathy peripheral	1	0	1
	Paraesthesia	2	13	15
	Parkinson's disease	0	1	1
	Parosmia	0	1	1
	Patient elopement	1	0	1
	Poor quality sleep	0	1	1
	Presyncope	4	12	16
	Sedation	2	0	2
	Seizure	0	1	1
	Sensory disturbance	1	1	2
	Sleep deficit	1	0	1
	Somnolence	2	1	3
	Speech disorder	0	2	2
	Syncope	11	0	11
	Taste disorder	0	1	1
	Thoracic outlet syndrome	1	0	1
	Tremor	2	1	3
	Unresponsive to stimuli	1	0	1
Psychiatric disorders	Agitation	3	2	5
	Anxiety	3	2	5
	Apathy	0	1	1
	Confusional state	2	5	7
	Depressed mood	0	1	1
	Disorientation	1	0	1
	Insomnia	1	2	3
	Restlessness	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
	Renal pain	1	0	1
	Urinary retention	1	0	1
Reproductive system and breast disorders	Pelvic pain	0	1	1
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	2	0	2
	Asthma	0	1	1
	Asthma exercise induced	1	0	1
	Bronchospasm	3	0	3
	Cheyne-Stokes respiration	1	0	1
	Cough	2	6	8
	Dry throat	1	0	1
	Dysphonia	1	1	2
	Dyspnoea	11	4	15
	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	2	10	12
	Pharyngeal swelling	2	1	3
	Pleural effusion	1	0	1
	Pneumonitis	1	0	1
	Productive cough	0	1	1
	Pulmonary embolism	1	0	1
	Pulmonary oedema	2	0	2
	Rales	1	0	1
	Respiration abnormal	1	0	1
	Respiratory disorder	12	15	27
	Respiratory distress	1	0	1
	Respiratory failure	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
	Cold sweat	1	0	1
	Dermatitis	0	1	1
	Dry skin	1	0	1
	Eczema	0	1	1
	Erythema	3	15	18
	Hyperhidrosis	1	4	5
	Livedo reticularis	1	0	1
	Pruritus	3	13	16
	Rash	2	8	10
	Rash erythematous	1	5	6
	Rash papular	0	1	1

	Rash pruritic	1	0	1
	Skin disorder	4	14	18
	Skin reaction	0	1	1
	Urticaria	2	5	7
Vascular disorders	Cyanosis	1	1	2
	Flushing	0	2	2
	Haematoma	1	3	4
	Hot flush	3	7	10
	Hypertension	8	7	15
	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
	Thrombophlebitis	1	0	1
	Thrombosis	1	0	1
	Vasculitis	0	1	1
Total		771	1889	2.660