

Summary Tabulation 16-03-2021

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	7	4	11
	Leukocytosis	1	0	1
	Lymph node pain	1	2	3
	Lymphadenitis	0	1	1
	Lymphadenopathy	18	18	36
	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	9	1	10
	Bundle branch block left	1	0	1
	Cardiac arrest	4	0	4
	Cardiac disorder	2	0	2
	Cardiac failure	3	0	3
	Cardio-respiratory arrest	3	0	3
	Cardiovascular disorder	38	14	52
	Coronary artery thrombosis	1	0	1
	Palpitations	7	9	16
	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	19	14	33
Ear and labyrinth disorders	Deafness unilateral	1	0	1
	Ear discomfort	0	1	1
	Ear pain	3	3	6
	Endolymphatic hydrops	2	0	2
	Hypoacusis	1	1	2
	Sudden hearing loss	1	0	1
	Tinnitus	5	1	6
	Vertigo	18	7	25
Vertigo positional	0	1	1	
Endocrine disorders	Goitre	0	1	1

Eye disorders	Abnormal sensation in eye	0	1	1	
	Asthenopia	0	2	2	
	Blindness	1	0	1	
	Diplopia	1	0	1	
	Eye irritation	0	1	1	
	Eye movement disorder	1	0	1	
	Eye pain	2	1	3	
	Eye swelling	3	1	4	
	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	5	2	7	
	Visual impairment	2	2	4	
	Vitreous floaters	0	1	1	
	Gastrointestinal disorders	Abdominal discomfort	1	2	3
		Abdominal distension	1	0	1
Abdominal pain		7	9	16	
Abdominal pain upper		3	3	6	
Anal incontinence		0	1	1	
Aphthous ulcer		1	1	2	
Breath odour		2	0	2	
Constipation		0	1	1	
Diarrhoea		16	25	41	
Dry mouth		2	1	3	
Dyspepsia		0	2	2	
Dysphagia		4	1	5	
Faeces discoloured		1	0	1	
Gastrointestinal disorder		1	0	1	
Gastrointestinal pain		2	1	3	
Gastrooesophageal reflux disease		0	1	1	
Gingival pain		1	0	1	
Glossodynia		0	1	1	
Hyperaesthesia teeth		1	0	1	
Hypoesthesia oral		0	1	1	
Intestinal dilatation		1	0	1	
Intestinal ischaemia		2	0	2	
Lip swelling		5	1	6	
Nausea		207	169	376	
Oral pruritus		0	1	1	
Paraesthesia oral		3	4	7	
Parotid gland enlargement		0	1	1	
Rectal haemorrhage		1	0	1	
Retching		3	0	3	
Salivary hypersecretion		2	0	2	
Stomatitis		1	1	2	
Swollen tongue		5	3	8	
Tongue discolouration		0	1	1	
Tongue discomfort		1	0	1	

	Vomiting	29	22	51
General disorders and administration site conditions	Asthenia	17	18	35
	Axillary pain	2	9	11
	Chest discomfort	8	1	9
	Chest pain	11	3	14
	Chills	242	185	427
	Crying	2	0	2
	Death	3	0	3
	Drug ineffective	3	0	3
	Drug resistance	1	0	1
	Exercise tolerance decreased	4	0	4
	Extensive swelling of vaccinated limb	1	0	1
	Face oedema	1	2	3
	Facial pain	0	1	1
	Fatigue	292	290	582
	Feeling abnormal	3	0	3
	Feeling cold	4	3	7
	Feeling drunk	0	1	1
	Feeling hot	1	7	8
	Feeling of body temperature change	3	10	13
	Gait disturbance	2	0	2
	Gait inability	0	3	3
	General physical health deterioration	13	0	13
	Hyperthermia	0	6	6
	Hypothermia	1	1	2
	Illness	2	0	2
	Inflammation	1	3	4
	Influenza like illness	38	24	62
	Injection site bruising	0	1	1
	Injection site discomfort	0	2	2
	Injection site erythema	10	63	73
	Injection site haematoma	1	7	8
	Injection site haemorrhage	0	1	1
	Injection site hypersensitivity	1	0	1
	Injection site hypoaesthesia	0	1	1
	Injection site induration	4	26	30
	Injection site inflammation	0	1	1
	Injection site movement impairment	1	1	2
	Injection site oedema	0	2	2
	Injection site pain	30	106	136
	Injection site paraesthesia	0	1	1
	Injection site pruritus	1	5	6
Injection site rash	0	3	3	
Injection site reaction	136	148	284	
Injection site swelling	8	27	35	
Injection site warmth	4	15	19	
Malaise	191	164	355	
Multiple organ dysfunction syndrome	1	0	1	
Oedema	0	1	1	
Pain	2	6	8	

	Peripheral swelling	27	57	84
	Pyrexia	232	255	487
	Secretion discharge	0	1	1
	Sensation of foreign body	2	0	2
	Sense of oppression	2	8	10
	Sudden death	15	0	15
	Swelling	1	6	7
	Swelling face	4	2	6
	Thirst	1	1	2
	Vaccination site erythema	0	2	2
	Vaccination site pain	1	4	5
	Vaccination site pruritus	0	1	1
	Vaccination site swelling	1	1	2
	Vaccination site warmth	0	1	1
Hepatobiliary disorders	Hepatitis	0	1	1
	Liver disorder	1	0	1
Immune system disorders	Anaphylactic reaction	23	3	26
	Anaphylactic shock	4	0	4
	Anaphylactoid reaction	1	0	1
	Autoimmune disorder	0	1	1
	Hypersensitivity	12	7	19
Infections and infestations	Appendicitis	2	0	2
	Asymptomatic COVID-19	1	0	1
	COVID-19	18	13	31
	COVID-19 pneumonia	1	0	1
	Ear infection	0	1	1
	Erysipelas	1	0	1
	Herpes ophthalmic	2	1	3
	Herpes simplex	1	0	1
	Herpes virus infection	0	1	1
	Herpes zoster	1	8	9
	Influenza	1	9	10
	Laryngitis	1	0	1
	Localised infection	1	0	1
	Nasopharyngitis	1	2	3
	Oral herpes	4	0	4
	Parapharyngeal space infection	1	0	1
	Pharyngitis	0	2	2
	Pneumonia	4	0	4
	Pneumonia bacterial	1	0	1
	Pyelonephritis	1	0	1
	Respiratory tract infection	2	0	2
	Rhinitis	1	2	3
	Rhinolaryngitis	0	1	1
	Scarlet fever	1	0	1
	Sepsis	2	0	2
	Septic shock	1	0	1
	Sinusitis	0	2	2
	Tonsillitis	0	1	1
	Urosepsis	1	0	1

	Vestibular neuronitis	1	0	1	
Injury, poisoning and procedural complications	Chillblains	1	0	1	
	Contusion	0	1	1	
	Drug administered in wrong device	0	1	1	
	Eschar	1	0	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	5	3	8	
	Blood pressure increased	6	2	8	
	Blood urine present	1	0	1	
	Body temperature fluctuation	1	0	1	
	Body temperature increased	5	7	12	
	Fibrin D dimer increased	1	0	1	
	Haemoglobin decreased	1	0	1	
	Heart rate decreased	2	0	2	
	Heart rate increased	6	1	7	
	Heart rate irregular	0	1	1	
	Liver function test abnormal	3	0	3	
	N-terminal prohormone brain natriuretic peptide	1	0	1	
	Oxygen saturation abnormal	1	0	1	
	Oxygen saturation decreased	23	3	26	
	Respiratory rate increased	1	0	1	
	SARS-CoV-2 test positive	2	0	2	
	Troponin increased	3	0	3	
	Weight decreased	1	0	1	
	Metabolism and nutrition disorders	Decreased appetite	5	9	14
		Dehydration	1	0	1
Diabetic complication		1	0	1	
Hypoglycaemia		4	2	6	
Ketoacidosis		3	0	3	
Metabolic acidosis		1	0	1	
Tetany		1	0	1	
Vitamin D deficiency		1	0	1	
Musculoskeletal and connective tissue disorders	Arthralgia	110	89	199	
	Arthritis	2	2	4	
	Axillary mass	1	0	1	
	Back pain	5	3	8	
	Bone pain	5	1	6	
	Groin pain	0	1	1	
	Jaw disorder	0	1	1	
	Joint stiffness	1	0	1	
	Joint swelling	1	1	2	
	Limb discomfort	5	0	5	
	Muscle spasms	1	2	3	

	Muscular weakness	3	6	9
	Musculoskeletal chest pain	0	2	2
	Musculoskeletal discomfort	0	1	1
	Musculoskeletal stiffness	15	29	44
	Myalgia	251	271	522
	Myosclerosis	0	1	1
	Neck pain	8	9	17
	Pain in extremity	16	57	73
	Pain in jaw	1	0	1
	Posture abnormal	0	1	1
	SAPHO syndrome	0	1	1
Nervous system disorders	Ageusia	0	3	3
	Allodynia	1	0	1
	Altered state of consciousness	4	2	6
	Amnesia	1	0	1
	Anosmia	1	3	4
	Aphasia	1	0	1
	Balance disorder	5	1	6
	Burning sensation	1	4	5
	Cerebral thrombosis	2	0	2
	Cerebrovascular accident	6	0	6
	Coma	2	0	2
	Depressed level of consciousness	10	0	10
	Disturbance in attention	0	2	2
	Dizziness	27	18	45
	Dysaesthesia	1	0	1
	Dysgeusia	8	9	17
	Dysstasia	1	0	1
	Dystonia	1	0	1
	Epilepsy	7	0	7
	Facial paralysis	6	0	6
	Facial paresis	8	0	8
	Facial spasm	0	2	2
	Formication	1	0	1
	Generalised tonic-clonic seizure	1	0	1
	Haemorrhage intracranial	1	0	1
	Haemorrhagic stroke	1	0	1
	Head discomfort	1	1	2
	Headache	306	299	605
	Hemianaesthesia	1	0	1
	Hemiparaesthesia	1	0	1
	Hemiplegia	3	0	3
	Hypersomnia	1	0	1
	Hypoaesthesia	4	8	12
	Hyporesponsive to stimuli	1	0	1
	Lethargy	1	0	1
	Loss of consciousness	4	0	4
	Memory impairment	1	0	1
	Migraine	11	6	17
	Migraine with aura	2	0	2

	Nervous system disorder	26	22	48
	Neuralgia	1	0	1
	Neuritis	1	0	1
	Neuropathy peripheral	1	0	1
	Orthostatic intolerance	1	0	1
	Paraesthesia	6	16	22
	Paralysis	1	0	1
	Parkinson's disease	2	0	2
	Parosmia	0	1	1
	Patient elopement	1	0	1
	Poor quality sleep	1	1	2
	Presyncope	7	14	21
	Sedation	3	0	3
	Seizure	7	0	7
	Sensory disturbance	1	1	2
	Sleep deficit	1	0	1
	Somnolence	4	2	6
	Speech disorder	0	2	2
	Syncope	17	3	20
	Taste disorder	0	1	1
	Thoracic outlet syndrome	1	0	1
	Tremor	6	2	8
	Unresponsive to stimuli	3	0	3
	Visual field defect	2	0	2
Psychiatric disorders	Agitation	5	2	7
	Anxiety	6	2	8
	Apathy	1	1	2
	Confusional state	4	8	12
	Depressed mood	0	1	1
	Disorientation	2	0	2
	Hallucination	3	0	3
	Hallucination, visual	0	1	1
	Insomnia	9	2	11
	Irritability	1	0	1
	Restlessness	1	1	2
	Sleep disorder	2	0	2
	Staring	1	0	1
Renal and urinary disorders	Acute kidney injury	2	0	2
	Polyuria	0	1	1
	Renal disorder	4	0	4
	Renal failure	3	0	3
	Renal pain	3	2	5
	Urinary retention	1	0	1
Reproductive system and breast disorders	Metrorrhagia	0	1	1
	Pelvic pain	0	1	1
	Vaginal haemorrhage	1	0	1
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1
	Acute respiratory failure	3	0	3
	Asthma	2	1	3
	Asthma exercise induced	1	0	1

Bradypnoea	1	0	1
Bronchial disorder	1	0	1
Bronchospasm	3	0	3
Cheyne-Stokes respiration	1	0	1
Cough	7	9	16
Dry throat	1	1	2
Dysphonia	2	1	3
Dyspnoea	29	5	34
Dyspnoea exertional	1	0	1
Epistaxis	1	4	5
Hyperventilation	2	0	2
Hypoxia	1	0	1
Laryngeal discomfort	0	1	1
Laryngeal oedema	0	1	1
Laryngospasm	1	0	1
Lung infiltration	1	0	1
Nasal congestion	0	1	1
Nasal discomfort	0	1	1
Oropharyngeal pain	7	13	20
Painful respiration	0	1	1
Pharyngeal swelling	4	2	6
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 arrest	1	0	1
Respiratory disorder	38	26	64
Respiratory distress	3	0	3
Respiratory failure	1	0	1
Rhinorrhoea	3	5	8
Sinus pain	1	0	1
Sneezing	2	1	3
Suffocation feeling	1	0	1
Tachypnoea	2	0	2
Throat tightness	2	0	2
Tonsillar inflammation	1	0	1
Upper airway obstruction	1	0	1
Wheezing	1	0	1
Skin and subcutaneous tissue disorders			
Angioedema	4	0	4
Cold sweat	1	0	1
Dermatitis	0	1	1
Dry skin	1	0	1
Eczema	0	1	1
Erythema	11	16	27
Hyperhidrosis	6	8	14

	Livedo reticularis	1	0	1
	Night sweats	1	0	1
	Pain of skin	1	0	1
	Palmoplantar pustulosis	0	1	1
	Pityriasis rosea	0	1	1
	Pruritus	12	17	29
	Rash	7	12	19
	Rash erythematous	1	8	9
	Rash macular	1	0	1
	Rash maculo-papular	1	0	1
	Rash papular	0	2	2
	Rash pruritic	1	0	1
	Sensitive skin	2	0	2
	Skin burning sensation	1	0	1
	Skin disorder	23	24	47
	Skin reaction	0	1	1
	Skin sensitisation	1	0	1
	Urticaria	5	6	11
	Urticaria papular	0	1	1
	Yellow skin	1	0	1
Social circumstances	Bedridden	1	0	1
	Immobile	0	1	1
Surgical and medical procedures	Coronary arterial stent insertion	1	0	1
Vascular disorders	Cyanosis	1	1	2
	Deep vein thrombosis	2	0	2
	Flushing	2	1	3
	Haematoma	2	4	6
	Haemorrhage	1	0	1
	Hot flush	8	11	19
	Hypertension	20	9	29
	Hypertensive crisis	1	0	1
	Hypotension	13	7	20
	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		3288	3057	6.345