

## Summary Tabulation 06-04-2021

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	13	4	17
	Leukocytosis	1	0	1
	Lymph node pain	1	2	3
	Lymphadenitis	0	1	1
	Lymphadenopathy	22	18	40
	Neutropenia	1	0	1
	Thrombocytopenia	3	0	3
Cardiac disorders	Angina pectoris	1	1	2
	Arrhythmia	3	0	3
	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	7	0	7
	Cardiac disorder	3	0	3
	Cardiac failure	4	0	4
	Cardio-respiratory arrest	3	0	3
	Cardiogenic shock	1	0	1
	Cardiomegaly	1	0	1
	Cardiovascular disorder	48	16	64
	Coronary artery thrombosis	1	0	1
	Palpitations	8	9	17
	Pericardial effusion	1	0	1
	Rhythm idioventricular	1	0	1
	Sinus tachycardia	1	0	1
	Stress cardiomyopathy	0	1	1
	Supraventricular tachycardia	1	0	1
	Tachyarrhythmia	1	0	1
	Tachycardia	24	16	40
	Ear and labyrinth disorders	Deafness unilateral	1	0
Ear discomfort		0	2	2
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	20	7	27
	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	2	0	2
	Diplopia	1	0	1
	Endocrine ophthalmopathy	0	1	1
	Eye irritation	1	1	2
	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	4	3	7
	Anal incontinence	0	1	1
	Aphthous ulcer	2	1	3
	Breath odour	2	0	2
	Constipation	0	1	1
	Diarrhoea	20	25	45
	Diarrhoea haemorrhagic	0	1	1
	Dry mouth	2	1	3
	Dyspepsia	1	2	3
	Dysphagia	4	2	6
	Faeces discoloured	1	0	1
	Gastrointestinal disorder	2	0	2
	Gastrointestinal pain	2	1	3
	Gastrooesophageal reflux disease	1	1	2
	Gingival pain	1	0	1
	Glossodynia	0	1	1
	Hyperaesthesia teeth	1	0	1
	Hypoaesthesia oral	0	1	1
	Intestinal dilatation	1	0	1
	Intestinal ischaemia	2	0	2
	Lip swelling	5	1	6
	Nausea	250	173	423
	Oral pruritus	0	1	1
	Paraesthesia oral	3	4	7
	Parotid gland enlargement	0	1	1
	Rectal haemorrhage	1	0	1
	Retching	4	0	4

	Salivary hypersecretion	2	0	2
	Stomatitis	1	1	2
	Swollen tongue	6	4	10
	Tongue discolouration	0	1	1
	Tongue discomfort	1	0	1
	Vomiting	31	23	54
General disorders and administration site conditions	Application site oedema	1	0	1
	Asthenia	20	19	39
	Axillary pain	4	9	13
	Chest discomfort	8	1	9
	Chest pain	14	3	17
	Chills	311	188	499
	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	3	1	4
	Face oedema	1	2	3
	Facial pain	0	1	1
	Fatigue	384	294	678
	Feeling abnormal	4	0	4
	Feeling cold	4	3	7
	Feeling drunk	0	1	1
	Feeling hot	2	7	9
	Feeling of body temperature change	4	10	14
	Gait disturbance	2	0	2
	Gait inability	0	3	3
	General physical health deterioration	13	0	13
	Hyperthermia	0	6	6
	Hypothermia	2	1	3
	Illness	2	0	2
	Inflammation	1	3	4
	Influenza like illness	46	24	70
	Injection site bruising	0	1	1
	Injection site discomfort	0	2	2
	Injection site erythema	11	64	75
	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	35	107	142
	Injection site paraesthesia	0	1	1
Injection site pruritus	1	5	6	
Injection site rash	0	3	3	
Injection site reaction	188	149	337	

	Injection site swelling	8	28	36
	Injection site warmth	5	15	20
	Malaise	244	168	412
	Multiple organ dysfunction syndrome	1	0	1
	Oedema	0	1	1
	Oedema peripheral	1	0	1
	Pain	4	6	10
	Peripheral swelling	35	57	92
	Pyrexia	305	258	563
	Secretion discharge	0	1	1
	Sensation of foreign body	2	0	2
	Sense of oppression	3	8	11
	Sudden death	17	0	17
	Swelling	1	6	7
	Swelling face	5	2	7
	Thirst	1	1	2
	Vaccination site erythema	1	2	3
	Vaccination site induration	1	0	1
	Vaccination site pain	2	4	6
	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	27	3	30
	Anaphylactic shock	4	0	4
	Anaphylactoid reaction	1	0	1
	Autoimmune disorder	3	3	6
	Food allergy	1	0	1
	Hypersensitivity	17	7	24
Infections and infestations	Appendicitis	2	0	2
	Asymptomatic COVID-19	1	0	1
	COVID-19	23	13	36
	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	1	1	2
	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	2	0	2

	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
	Facial bones fracture	1	0	1
	Fall	8	0	8
	Inappropriate schedule of product	0	1	1
	Incorrect dose administered	0	1	1
	Incorrect route of product administration	0	1	1
	Vaccination failure	2	0	2
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	2	0	2
	Blood pressure decreased	7	3	10
	Blood pressure increased	7	2	9
	Blood test abnormal	1	0	1
	Blood urine present	1	0	1
	Body temperature fluctuation	1	0	1
	Body temperature increased	6	7	13
	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	1	0	1
	Oxygen saturation abnormal	1	0	1
	Oxygen saturation decreased	26	4	30
	Prohormone brain natriuretic peptide increased	1	0	1
	Respiratory rate increased	1	0	1
	SARS-CoV-2 test positive	2	0	2
	Troponin T increased	1	0	1
	Troponin increased	3	0	3
	Weight decreased	1	0	1
Metabolism and nutrition disorders	Decreased appetite	6	9	15
	Dehydration	1	0	1
	Diabetic complication	1	0	1
	Hypoglycaemia	4	2	6

	Ketoacidosis	3	0	3
	Lactic acidosis	1	0	1
	Metabolic acidosis	1	0	1
	Tetany	1	0	1
	Vitamin D deficiency	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	147	93	240
	Arthritis	2	2	4
	Axillary mass	1	0	1
	Back pain	6	4	10
	Bone pain	5	2	7
	Groin pain	0	1	1
	Jaw disorder	0	1	1
	Joint stiffness	1	0	1
	Joint swelling	1	1	2
	Limb discomfort	6	0	6
	Muscle spasms	1	2	3
	Muscular weakness	3	6	9
	Musculoskeletal chest pain	0	2	2
	Musculoskeletal discomfort	0	1	1
	Musculoskeletal stiffness	16	29	45
	Myalgia	320	275	595
	Myosclerosis	0	1	1
	Neck pain	10	9	19
	Pain in extremity	21	58	79
	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	6	1	7
	Burning sensation	3	4	7
	Cerebral haemorrhage	1	0	1
	Cerebral ischaemia	1	0	1
	Cerebral thrombosis	2	0	2
	Cerebrovascular accident	9	0	9
	Coma	2	0	2
	Depressed level of consciousness	10	0	10
	Disturbance in attention	1	2	3
	Dizziness	32	19	51
	Dysaesthesia	1	0	1
	Dysgeusia	8	9	17
	Dysstasia	1	0	1
	Dystonia	1	0	1
	Epilepsy	7	0	7
	Facial paralysis	10	0	10
	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	403	304	707
	Hemianaesthesia	1	0	1
	Hemiparaesthesia	1	0	1
	Hemiplegia	3	0	3
	Hyperaesthesia	1	0	1
	Hypersomnia	1	0	1
	Hypoaesthesia	6	9	15
	Hyporesponsive to stimuli	1	0	1
	Lethargy	1	0	1
	Loss of consciousness	5	0	5
	Memory impairment	1	0	1
	Migraine	14	6	20
	Migraine with aura	2	0	2
	Nervous system disorder	29	24	53
	Neuralgia	1	0	1
	Neuritis	1	0	1
	Neuropathy peripheral	1	0	1
	Orthostatic intolerance	1	0	1
	Paraesthesia	8	18	26
	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	8	1	9
	Sensory disturbance	1	1	2
	Sleep deficit	1	0	1
	Somnolence	4	2	6
	Speech disorder	1	2	3
	Syncope	21	4	25
	Taste disorder	1	1	2
	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	2	1	3
	Confusional state	4	8	12
	Depressed mood	0	1	1
	Disorientation	2	0	2
	Hallucination	3	0	3

	Hallucination, visual	0	1	1
	Insomnia	13	2	15
	Irritability	1	0	1
	Nightmare	1	0	1
	Restlessness	1	1	2
	Sleep disorder	2	0	2
	Staring	1	0	1
Renal and urinary disorders	Acute kidney injury	3	0	3
	Polyuria	0	1	1
	Renal disorder	6	0	6
	Renal failure	3	0	3
	Renal pain	3	2	5
	Urinary retention	1	0	1
Reproductive system and breast disorders	Breast pain	1	0	1
	Metrorrhagia	0	1	1
	Pelvic pain	0	1	1
	Suppressed lactation	1	0	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	9	9	18
	Dry throat	1	1	2
	Dysphonia	2	2	4
	Dyspnoea	38	5	43
	Dyspnoea exertional	1	0	1
	Epistaxis	2	4	6
	Hyperventilation	3	0	3
	Hypoxia	1	0	1
	Laryngeal discomfort	0	1	1
	Laryngeal oedema	0	1	1
	Laryngospasm	1	0	1
	Lower respiratory tract congestion	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	1	1	2
	Pharyngeal swelling	4	3	7
	Pleural effusion	2	0	2
	Pneumonia aspiration	1	0	1
	Pneumonitis	1	0	1
	Productive cough	0	1	1
	Pulmonary arterial hypertension	1	0	1
	Pulmonary embolism	6	0	6



	Pulmonary infarction	1	0	1
	Pulmonary oedema	3	0	3
	Rales	2	0	2
	Respiration abnormal	2	0	2
	Respiratory acidosis	1	0	1
	Respiratory arrest	1	0	1
	Respiratory disorder	54	28	82
	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	3	0	3
	Tonsillar inflammation	1	0	1
	Upper airway obstruction	1	0	1
	Wheezing	2	0	2
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	13	16	29
	Hyperhidrosis	7	8	15
	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	16	17	33
	Rash	7	12	19
	Rash erythematous	2	8	10
	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	29	24	53
	Skin reaction	0	1	1
	Skin sensitisation	1	0	1
	Urticaria	6	6	12
	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
	Resuscitation	1	0	1
Vascular disorders	Cyanosis	1	1	2

Deep vein thrombosis	5	0	5
Flushing	2	1	3
Haematoma	2	4	6
Haemorrhage	1	0	1
Hot flush	9	12	21
Hypertension	29	10	39
Hypertensive crisis	1	0	1
Hypotension	14	7	21
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
Vein rupture	1	0	1
<b>Total</b>	<b>4137</b>	<b>3125</b>	<b>7 262</b>