

### Summary Tabulation 20.04.2021

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	15	4	19
	Leukocytosis	1	0	1
	Lymph node pain	1	2	3
	Lymphadenitis	0	1	1
	Lymphadenopathy	25	21	46
	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	8	0	8
	Cardiac disorder	3	0	3
	Cardiac failure	4	0	4
	Cardio-respiratory arrest	3	0	3
	Cardiogenic shock	2	0	2
	Cardiomegaly	1	0	1
	Cardiovascular disorder	52	17	69
	Coronary artery thrombosis	1	0	1
	Palpitations	10	10	20
	Pericardial effusion	1	0	1
	Pericarditis	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	28	16	44	
Ear and labyrinth disorders	Deafness	1	0	1
	Deafness unilateral	1	0	1
	Dysacusis	1	0	1
	Ear discomfort	1	2	3

	Ear pain	5	3	8
	Endolymphatic hydrops	2	0	2
	Hypoacusis	1	1	2
	Sudden hearing loss	1	0	1
	Tinnitus	6	3	9
	Vertigo	23	7	30
	Vertigo positional	0	1	1
Endocrine disorders	Goitre	0	1	1
	Thyroid mass	0	1	1
Eye disorders	Abnormal sensation in eye	0	1	1
	Asthenopia	1	2	3
	Blindness	2	0	2
	Diplopia	2	0	2
	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
	Lacrimation increased	1	0	1
	Mydriasis	0	1	1
	Ocular hyperaemia	1	0	1
	Photophobia	1	0	1
	Photopsia	1	1	2
	Swelling of eyelid	1	0	1
	Vision blurred	5	2	7
	Visual impairment	4	2	6
	Vitreous floaters	0	1	1
Gastrointestinal disorders	Abdominal discomfort	1	4	5
	Abdominal distension	1	1	2
	Abdominal pain	8	10	18
	Abdominal pain upper	4	3	7
	Anal incontinence	0	1	1
	Aphthous ulcer	2	1	3
	Breath odour	2	0	2
	Constipation	1	1	2
	Diarrhoea	28	25	53
	Diarrhoea haemorrhagic	0	1	1
	Dry mouth	3	1	4
	Dyspepsia	1	2	3
	Dysphagia	5	2	7
	Faecal vomiting	1	0	1
	Faeces discoloured	1	0	1
	Flatulence	0	2	2
	Gastric dilatation	1	0	1
	Gastrointestinal disorder	2	0	2
	Gastrointestinal pain	3	1	4
	Gastrooesophageal reflux disease	1	1	2
	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
Intestinal obstruction	1	0	1
Lip swelling	6	1	7
Nausea	289	178	467
Oral pruritus	0	1	1
Paraesthesia oral	4	4	8
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	38	23	61
General disorders and administration site conditions			
Application site oedema	1	0	1
Asthenia	25	21	46
Axillary pain	6	9	15
Chest discomfort	8	1	9
Chest pain	17	3	20
Chills	366	191	557
Condition aggravated	0	1	1
Crying	2	0	2
Death	5	0	5
Drug ineffective	4	0	4
Drug resistance	1	0	1
Exercise tolerance decreased	4	0	4
Extensive swelling of vaccinated limb	9	1	10
Face oedema	1	2	3
Facial pain	0	1	1
Fatigue	442	300	742
Feeling abnormal	5	1	6
Feeling cold	4	3	7
Feeling drunk	0	1	1
Feeling hot	3	7	10
Feeling of body temperature change	5	10	15
Gait disturbance	2	0	2
Gait inability	1	3	4
General physical health deterioration	16	0	16
Hyperthermia	0	6	6
Hypothermia	2	1	3
Illness	1	1	2
Inflammation	1	3	4
Influenza like illness	55	26	81
Injection site bruising	0	1	1
Injection site discomfort	0	3	3
Injection site erythema	13	64	77

	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	5	26	31
	Injection site inflammation	0	1	1
	Injection site movement impairment	1	1	2
	Injection site oedema	0	2	2
	Injection site pain	36	107	143
	Injection site paraesthesia	0	1	1
	Injection site pruritus	1	5	6
	Injection site rash	0	3	3
	Injection site reaction	220	151	371
	Injection site swelling	10	28	38
	Injection site warmth	5	15	20
	Malaise	276	169	445
	Multiple organ dysfunction syndrome	2	0	2
	Oedema	0	1	1
	Oedema peripheral	1	0	1
	Pain	4	6	10
	Peripheral swelling	36	58	94
	Pyrexia	350	262	612
	Secretion discharge	0	1	1
	Sensation of foreign body	2	0	2
	Sense of oppression	3	8	11
	Sudden death	18	0	18
	Swelling	2	6	8
	Swelling face	5	2	7
	Thirst	1	1	2
	Vaccination site erythema	1	3	4
	Vaccination site induration	1	0	1
	Vaccination site pain	2	8	10
	Vaccination site pruritus	0	1	1
	Vaccination site swelling	1	2	3
	Vaccination site warmth	0	2	2
Hepatobiliary disorders	Hepatic failure	1	0	1
	Hepatitis	1	1	2
	Liver disorder	3	0	3
Immune system disorders	Anaphylactic reaction	28	3	31
	Anaphylactic shock	4	0	4
	Anaphylactoid reaction	1	0	1
	Autoimmune disorder	4	3	7
	Food allergy	1	0	1
	Hypersensitivity	17	7	24
Infections and infestations	Abscess	1	0	1
	Appendicitis	2	0	2
	Asymptomatic COVID-19	1	0	1
	COVID-19	24	14	38
	COVID-19 pneumonia	1	0	1
	Diverticulitis	0	1	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	2	9	11
	Hordeolum	1	0	1
	Influenza	1	10	11
	Laryngitis	1	0	1
	Localised infection	1	0	1
	Nasopharyngitis	2	2	4
	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	2	0	2
	Sinusitis	0	2	2
	Tonsillitis	0	1	1
	Urosepsis	1	0	1
	Vaginal abscess	1	0	1
	Vestibular neuronitis	1	0	1
Injury, poisoning and procedural complications	Chillblains	1	0	1
	Contusion	0	2	2
	Drug administered in wrong device	0	1	1
	Eschar	1	0	1
	Facial bones fracture	1	0	1
	Fall	10	0	10
	Inappropriate schedule of product administration	0	1	1
	Incorrect dose administered	0	1	1
	Incorrect route of product administration	0	1	1
	Vaccination failure	2	0	2
	Wrong product administered	1	0	1
	Investigations	Alanine aminotransferase increased	0	1
Aspartate aminotransferase increased		0	1	1
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		10	3	13
Blood pressure increased		8	2	10
Blood test abnormal		1	0	1
Blood urine present		1	0	1

	Body temperature fluctuation	1	0	1
	Body temperature increased	6	8	14
	Fibrin D dimer increased	1	0	1
	Gamma-glutamyltransferase increased	0	1	1
	Haemoglobin decreased	1	0	1
	Heart rate decreased	2	0	2
	Heart rate increased	7	1	8
	Heart rate irregular	0	1	1
	Hepatic enzyme increased	0	1	1
	Liver function test abnormal	3	1	4
	N-terminal prohormone brain natriuretic peptide	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
	White blood cell count decreased	1	0	1
Metabolism and nutrition disorders	Decreased appetite	8	9	17
	Dehydration	1	0	1
	Diabetic complication	1	0	1
	Hyperglycaemia	1	0	1
	Hypoglycaemia	5	2	7
	Ketoacidosis	3	0	3
	Lactic acidosis	2	0	2
	Metabolic acidosis	1	0	1
	Tetany	1	0	1
	Vitamin D deficiency	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	170	93	263
	Arthritis	3	2	5
	Axillary mass	1	0	1
	Back pain	8	4	12
	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	8	0	8
	Muscle spasms	1	2	3
	Muscular weakness	3	6	9
	Musculoskeletal chest pain	0	2	2
	Musculoskeletal discomfort	0	1	1
	Musculoskeletal stiffness	19	39	58
	Myalgia	365	280	645
	Myosclerosis	0	1	1
	Neck pain	12	10	22
	Pain in extremity	25	62	87
	Pain in jaw	1	0	1

	Posture abnormal	0	1	1
	SAPHO syndrome	0	1	1
	Tendonitis	1	0	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	2	0	2
	Balance disorder	8	1	9
	Burning sensation	4	4	8
	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	36	20	56	
Dysaesthesia	1	0	1	
Dysgeusia	10	9	19	
Dyspraxia	1	0	1	
Dysstasia	1	0	1	
Dystonia	1	0	1	
Epilepsy	8	1	9	
Facial paralysis	11	0	11	
Facial paresis	8	0	8	
Facial spasm	0	2	2	
Formication	1	0	1	
Generalised tonic-clonic seizure	3	0	3	
Haemorrhage intracranial	1	0	1	
Haemorrhagic stroke	1	0	1	
Head discomfort	2	1	3	
Headache	463	313	776	
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	2	0	2	
Migraine	15	6	21	
Migraine with aura	2	0	2	
Muscle contractions involuntary	1	0	1	
Nervous system disorder	35	24	59	
Neuralgia	1	0	1	
Neuritis	1	0	1	

	Neuropathy peripheral	1	0	1
	Orthostatic intolerance	1	0	1
	Paraesthesia	10	18	28
	Paralysis	1	0	1
	Parkinson's disease	2	0	2
	Parosmia	0	1	1
	Patient elopement	1	0	1
	Peripheral motor neuropathy	1	0	1
	Poor quality sleep	1	1	2
	Presyncope	8	14	22
	Sedation	3	0	3
	Seizure	9	1	10
	Sensory disturbance	1	1	2
	Sleep deficit	1	0	1
	Somnolence	6	2	8
	Speech disorder	3	3	6
	Syncope	22	4	26
	Taste disorder	1	1	2
	Thoracic outlet syndrome	1	0	1
	Transient ischaemic attack	1	0	1
	Tremor	7	2	9
	Unresponsive to stimuli	3	0	3
	Visual field defect	2	0	2
Psychiatric disorders	Acute psychosis	1	0	1
	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	4	0	4
	Hallucination, visual	0	1	1
	Insomnia	14	3	17
	Irritability	1	0	1
	Nightmare	1	0	1
	Restlessness	1	1	2
	Sleep disorder	2	1	3
	Staring	1	0	1
Renal and urinary disorders	Acute kidney injury	3	0	3
	Polyuria	1	1	2
	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	2	0	2
	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



disorders

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	12	9	21
Dry throat	1	1	2
Dysphonia	2	2	4
Dyspnoea	42	5	47
Dyspnoea exertional	1	0	1
Epistaxis	2	4	6
Haemoptysis	1	0	1
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	1	1	2
Nasal discomfort	0	1	1
Oropharyngeal pain	8	14	22
Painful respiration	1	1	2
Pharyngeal paraesthesia	1	0	1
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	8	0	8
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	64	28	92
Respiratory distress	3	0	3
Respiratory failure	1	0	1
Rhinorrhoea	6	5	11
Sinus pain	1	0	1
Sneezing	3	2	5
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	14	16	30
	Hyperhidrosis	10	8	18
	Livedo reticularis	1	0	1
	Night sweats	1	0	1
	Pain of skin	3	0	3
	Palmoplantar pustulosis	0	1	1
	Pityriasis rosea	0	1	1
	Pruritus	19	17	36
	Rash	8	12	20
	Rash erythematous	2	8	10
	Rash macular	2	0	2
	Rash maculo-papular	1	0	1
	Rash papular	0	2	2
	Rash pruritic	1	0	1
	Sensitive skin	3	1	4
	Skin burning sensation	1	0	1
	Skin disorder	34	24	58
	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	2	1	3
	Deep vein thrombosis	6	0	6
	Flushing	2	1	3
	Haematoma	2	4	6
	Haemorrhage	1	0	1
	Hot flush	11	12	23
	Hypertension	30	10	40
	Hypertensive crisis	1	0	1
	Hypotension	15	7	22
	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
	Thrombophlebitis superficial	0	1	1
	Thrombosis	2	0	2
	Vasculitis	0	1	1

	Vein rupture	1	0	1
<b>Total</b>		<b>4763</b>	<b>3225</b>	<b>7.988</b>

Rows 1 - 487 (All Rows)