

Summary Tabulation 30.03.21

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	9	4	13
	Leukocytosis	1	0	1
	Lymph node pain	1	2	3
	Lymphadenitis	0	1	1
	Lymphadenopathy	21	18	39
	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	7	0	7
	Cardiac disorder	3	0	3
	Cardiac failure	3	0	3
	Cardio-respiratory arrest	3	0	3
	Cardiovascular disorder	42	15	57
	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
	Supraventricular tachycardia	1	0	1
	Tachyarrhythmia	1	0	1
Tachycardia	23	15	38	
Ear and labyrinth disorders	Deafness unilateral	1	0	1
	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	1	1	2
	Breath odour	2	0	2
	Constipation	0	1	1
	Diarrhoea	19	25	44
	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	0	1	1
	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	237	173	410
	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	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	19	18	37
	Axillary pain	3	9	12
	Chest discomfort	8	1	9
	Chest pain	13	3	16
	Chills	285	186	471
	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	350	292	642
	Feeling abnormal	3	0	3
	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	44	24	68
	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	33	106	139
	Injection site paraesthesia	0	1	1
	Injection site pruritus	1	5	6
	Injection site rash	0	3	3
	Injection site reaction	170	149	319
	Injection site swelling	8	28	36
	Injection site warmth	5	15	20

	Malaise	227	167	394
	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	282	257	539
	Secretion discharge	0	1	1
	Sensation of foreign body	2	0	2
	Sense of oppression	2	8	10
	Sudden death	16	0	16
	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	2	2	4
	Hypersensitivity	17	7	24
Infections and infestations	Appendicitis	2	0	2
	Asymptomatic COVID-19	1	0	1
	COVID-19	21	13	34
	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	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
	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	1	0	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	2	0	2
	Blood pressure decreased	5	3	8
	Blood pressure increased	7	2	9
	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
	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	6	9	15
	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	134	91	225
	Arthritis	2	2	4

Axillary mass	1	0	1
Back pain	6	3	9
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	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	15	29	44
Myalgia	291	272	563
Myosclerosis	0	1	1
Neck pain	9	9	18
Pain in extremity	20	57	77
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 thrombosis	2	0	2
Cerebrovascular accident	7	0	7
Coma	2	0	2
Depressed level of consciousness	10	0	10
Disturbance in attention	1	2	3
Dizziness	31	19	50
Dysaesthesia	1	0	1
Dysgeusia	8	9	17
Dysstasia	1	0	1
Dystonia	1	0	1
Epilepsy	7	0	7
Facial paralysis	8	0	8
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	368	302	670
Hemianaesthesia	1	0	1

	Hemiparaesthesia	1	0	1
	Hemiplegia	3	0	3
	Hyperaesthesia	1	0	1
	Hypersomnia	1	0	1
	Hypoesthesia	5	8	13
	Hyporesponsive to stimuli	1	0	1
	Lethargy	1	0	1
	Loss of consciousness	5	0	5
	Memory impairment	1	0	1
	Migraine	13	6	19
	Migraine with aura	2	0	2
	Nervous system disorder	28	23	51
	Neuralgia	1	0	1
	Neuritis	1	0	1
	Neuropathy peripheral	1	0	1
	Orthostatic intolerance	1	0	1
	Paraesthesia	8	17	25
	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	18	4	22
	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	11	2	13
	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	2	0	2

	Polyuria	0	1	1
	Renal disorder	5	0	5
	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	8	9	17
	Dry throat	1	1	2
	Dysphonia	2	2	4
	Dyspnoea	34	5	39
	Dyspnoea exertional	1	0	1
	Epistaxis	1	4	5
	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 embolism	5	0	5
	Pulmonary infarction	1	0	1
	Pulmonary oedema	2	0	2
	Rales	2	0	2
	Respiration abnormal	2	0	2
	Respiratory arrest	1	0	1
	Respiratory disorder	48	26	74
	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	27	24	51
	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	3	0	3
	Flushing	2	1	3
	Haematoma	2	4	6
	Haemorrhage	1	0	1
	Hot flush	9	12	21
	Hypertension	25	9	34
	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
Total		3843	3098	6.941