

Summary Tabulation 04.05.2021

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	27	8	35
	Leukocytosis	2	0	2
	Lymph node pain	1	2	3
	Lymphadenitis	0	1	1
	Lymphadenopathy	28	22	50
	Microangiopathic haemolytic anaemia	1	0	1
	Neutropenia	1	0	1
	Thrombocytopenia	7	3	10
Cardiac disorders	Angina pectoris	2	1	3
	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	9	0	9
	Cardiac disorder	4	0	4
	Cardiac failure	4	0	4
	Cardio-respiratory arrest	3	0	3
	Cardiogenic shock	2	0	2
	Cardiomegaly	1	0	1
	Cardiovascular disorder	56	17	73
	Coronary artery thrombosis	1	0	1
	Extrasystoles	1	0	1
	Palpitations	14	10	24
	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	29	16	45
	Ear and labyrinth disorders	Deafness	1	0
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
	Meniere's disease	0	1	1
	Sudden hearing loss	1	0	1
	Tinnitus	6	3	9
	Vertigo	24	9	33
	Vertigo positional	0	1	1
	Vestibular disorder	1	0	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	4	3	7
	Eye swelling	4	1	5
	Glaucoma	1	0	1
	Iridocyclitis	0	1	1
	Lacrimation increased	1	0	1
	Mydriasis	0	1	1
	Ocular discomfort	0	2	2
	Ocular hyperaemia	1	0	1
	Photophobia	1	0	1
	Photopsia	1	1	2
	Retinal pigment epitheliopathy	1	0	1
	Swelling of eyelid	1	0	1
	Vision blurred	6	2	8
	Visual field defect	2	0	2
	Visual impairment	7	2	9
	Vitreous floaters	0	1	1
Gastrointestinal disorders	Abdominal discomfort	1	4	5
	Abdominal distension	1	1	2
	Abdominal pain	11	11	22
	Abdominal pain upper	9	3	12
	Anal incontinence	0	1	1
	Aphthous ulcer	2	1	3
	Breath odour	2	0	2
	Constipation	1	1	2
	Diarrhoea	34	26	60
	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	2	0	2
Gastrointestinal disorder	2	1	3
Gastrointestinal pain	4	1	5
Gastroesophageal reflux disease	1	1	2
Gingival pain	1	0	1
Glossodynia	0	1	1
Hyperaesthesia teeth	1	0	1
Hypoaesthesia oral	0	2	2
Intestinal dilatation	1	0	1
Intestinal ischaemia	2	0	2
Intestinal obstruction	1	0	1
Lip swelling	6	1	7
Nausea	332	184	516
Oral pruritus	0	1	1
Pancreatitis	1	0	1
Paraesthesia oral	5	5	10
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
Tongue oedema	1	0	1
Vomiting	44	25	69
General disorders and administration site conditions			
Application site oedema	1	0	1
Asthenia	28	21	49
Axillary pain	8	9	17
Chest discomfort	10	1	11
Chest pain	25	3	28
Chills	428	195	623
Condition aggravated	1	1	2
Crying	2	0	2
Death	10	0	10
Discomfort	2	0	2
Drug ineffective	4	0	4
Drug resistance	1	0	1
Exercise tolerance decreased	4	0	4
Extensive swelling of vaccinated limb	19	1	20
Face oedema	1	2	3
Facial pain	0	1	1
Fatigue	521	311	832
Feeling abnormal	8	2	10
Feeling cold	5	3	8
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	17	0	17
Hangover	1	0	1
Hyperthermia	0	6	6
Hypothermia	3	1	4
Illness	1	1	2
Induration	0	1	1
Inflammation	2	4	6
Influenza like illness	61	28	89
Injection site bruising	1	1	2
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	41	108	149
Injection site paraesthesia	0	1	1
Injection site pruritus	1	5	6
Injection site rash	0	3	3
Injection site reaction	263	153	416
Injection site swelling	10	28	38
Injection site warmth	5	15	20
Malaise	310	175	485
Multiple organ dysfunction syndrome	2	0	2
Oedema	0	1	1
Oedema peripheral	1	0	1
Pain	8	6	14
Peripheral swelling	37	58	95
Pyrexia	404	270	674
Secretion discharge	0	1	1
Sensation of foreign body	2	0	2
Sense of oppression	3	8	11
Sudden death	22	0	22
Swelling	2	6	8
Swelling face	5	2	7
Therapeutic response unexpected	1	0	1
Thirst	2	1	3
Vaccination failure	3	0	3
Vaccination site erythema	1	3	4
Vaccination site induration	1	0	1
Vaccination site pain	2	11	13
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	2	1	3

	Liver disorder	7	0	7
Immune system disorders	Allergic reaction to excipient	0	1	1
	Anaphylactic reaction	28	3	31
	Anaphylactic shock	5	0	5
	Anaphylactoid reaction	1	0	1
	Autoimmune disorder	5	3	8
	Food allergy	1	0	1
	Hypersensitivity	17	8	25
Infections and infestations	Abscess	1	0	1
	Appendicitis	2	0	2
	Asymptomatic COVID-19	1	0	1
	COVID-19	31	14	45
	COVID-19 pneumonia	2	0	2
	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
	Infection	1	0	1
	Influenza	2	10	12
	Laryngitis	1	0	1
	Localised infection	1	0	1
	Nasopharyngitis	2	2	4
	Ophthalmic herpes zoster	1	0	1
	Oral herpes	5	0	5
	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	Brain contusion	1	0	1
	Chest injury	1	0	1
	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	11	0	11
	Inappropriate schedule of product administration	0	1	1
	Incorrect dose administered	0	1	1
	Incorrect route of product administration	0	1	1
	Subdural haematoma	1	0	1
	Wrong product administered	1	0	1
Investigations	Alanine aminotransferase increased	0	1	1
	Aspartate aminotransferase increased	0	1	1
	Blood alkaline phosphatase increased	1	0	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	4	14
	Blood pressure increased	9	2	11
	Blood test abnormal	1	0	1
	Blood urine present	1	0	1
	Body temperature fluctuation	1	0	1
	Body temperature increased	7	8	15
	C-reactive protein increased	1	1	2
	Fibrin D dimer increased	3	0	3
	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
	International normalised ratio increased	1	0	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	28	4	32
	Platelet count decreased	1	0	1
	Prohormone brain natriuretic peptide increased	1	0	1
	Respiratory rate increased	1	0	1
	SARS-CoV-2 antibody test negative	1	0	1
	SARS-CoV-2 test positive	3	0	3
	Troponin T increased	1	0	1
	Troponin increased	3	0	3
	Weight decreased	2	0	2
	White blood cell count decreased	1	0	1
Metabolism and nutrition disorders	Decreased appetite	14	9	23
	Dehydration	1	0	1
	Diabetic complication	1	0	1
	Hyperferritinaemia	1	0	1
	Hyperglycaemia	2	0	2
	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	202	99	301
	Arthritis	3	2	5
	Axillary mass	1	0	1
	Back pain	13	4	17
	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	11	0	11
	Muscle disorder	1	0	1
	Muscle spasms	1	2	3
	Muscular weakness	3	6	9
	Musculoskeletal chest pain	0	2	2
	Musculoskeletal discomfort	0	1	1
	Musculoskeletal stiffness	21	42	63
	Myalgia	429	288	717
	Myosclerosis	0	1	1
	Neck pain	12	10	22
	Neuropathic muscular atrophy	1	0	1
	Pain in extremity	30	66	96
	Pain in jaw	1	0	1
	Posture abnormal	0	1	1
	SAPHO syndrome	0	1	1
	Spinal pain	1	0	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	6	0	6
	Balance disorder	9	2	11
	Bell's palsy	2	0	2
	Brain injury	1	0	1
	Burning sensation	5	4	9
	Carotid artery occlusion	2	0	2
	Carotid artery thrombosis	1	0	1
	Cerebral haemorrhage	1	0	1
	Cerebral ischaemia	2	0	2
	Cerebral thrombosis	3	0	3
	Cerebrovascular accident	13	0	13
	Coma	2	0	2
	Depressed level of consciousness	10	0	10
	Disturbance in attention	2	3	5
	Dizziness	41	21	62

Dysaesthesia	1	0	1
Dysgeusia	10	10	20
Dyspraxia	1	0	1
Dysstasia	1	0	1
Dystonia	1	0	1
Electric shock sensation	2	0	2
Epilepsy	9	1	10
Facial nerve disorder	1	0	1
Facial paralysis	11	0	11
Facial paresis	9	0	9
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
Haemorrhagic transformation stroke	1	0	1
Head discomfort	2	1	3
Headache	532	323	855
Hemianaesthesia	1	0	1
Hemiparaesthesia	1	0	1
Hemiparesis	1	0	1
Hemiplegia	8	0	8
Hyperaesthesia	2	0	2
Hypersomnia	1	0	1
Hypoaesthesia	7	11	18
Hyporesponsive to stimuli	1	0	1
Ischaemic cerebral infarction	1	0	1
Ischaemic stroke	3	0	3
Lethargy	1	0	1
Loss of consciousness	7	0	7
Memory impairment	2	0	2
Migraine	15	7	22
Migraine with aura	2	0	2
Monoplegia	1	0	1
Motor dysfunction	1	0	1
Muscle contractions involuntary	1	0	1
Nerve compression	1	0	1
Nervous system disorder	44	26	70
Neuralgia	1	0	1
Neuritis	1	0	1
Neuropathy peripheral	1	0	1
Noninfective encephalitis	1	0	1
Orthostatic intolerance	1	0	1
Paraesthesia	11	20	31
Paralysis	1	0	1
Parkinson's disease	2	0	2
Parosmia	1	1	2
Patient elopement	1	0	1
Peripheral motor neuropathy	1	0	1
Presyncope	9	14	23

	Psychomotor hyperactivity	1	0	1
	Sedation	3	0	3
	Seizure	11	2	13
	Sensory disturbance	1	1	2
	Sleep deficit	1	0	1
	Somnolence	6	2	8
	Speech disorder	4	3	7
	Syncope	24	4	28
	Taste disorder	3	1	4
	Thoracic outlet syndrome	1	0	1
	Transient ischaemic attack	1	0	1
	Tremor	8	2	10
	Trigeminal neuralgia	1	0	1
	Unresponsive to stimuli	3	0	3
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	1	0	1
Psychiatric disorders	Abnormal dreams	1	0	1
	Acute psychosis	1	0	1
	Aggression	1	0	1
	Agitation	5	2	7
	Anxiety	6	2	8
	Apathy	2	1	3
	Attention deficit hyperactivity disorder	1	0	1
	Confusional state	5	9	14
	Delirium	1	0	1
	Delusion	0	1	1
	Depressed mood	0	1	1
	Disorientation	2	0	2
	Hallucination	4	1	5
	Hallucination, visual	0	1	1
	Insomnia	18	4	22
	Irritability	1	0	1
	Nightmare	1	0	1
	Poor quality sleep	1	1	2
	Restlessness	1	1	2
	Sleep disorder	2	2	4
	Staring	1	0	1
Renal and urinary disorders	Acute kidney injury	5	0	5
	Haematuria	1	0	1
	Polyuria	1	1	2
	Renal disorder	7	0	7
	Renal failure	3	0	3
	Renal pain	4	2	6
	Urinary retention	1	0	1
Reproductive system and breast disorders	Breast pain	2	0	2
	Intermenstrual bleeding	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	14	9	23
Dry throat	1	1	2
Dysphonia	2	3	5
Dyspnoea	46	5	51
Dyspnoea exertional	3	0	3
Epistaxis	2	6	8
Haemoptysis	2	0	2
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	2	0	2
Pneumonitis	1	0	1
Productive cough	2	1	3
Pulmonary arterial hypertension	1	0	1
Pulmonary embolism	15	0	15
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	2	0	2
Respiratory disorder	67	28	95
Respiratory distress	3	0	3
Respiratory failure	2	0	2
Rhinitis allergic	1	0	1
Rhinorrhoea	6	6	12
Sinus pain	1	0	1
Sneezing	4	2	6
Suffocation feeling	1	0	1
Tachypnoea	3	0	3
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	5	0	5
	Cold sweat	1	0	1
	Cutaneous vasculitis	2	0	2
	Dermatitis	0	1	1
	Dry skin	1	0	1
	Eczema	0	2	2
	Erythema	17	17	34
	Hyperhidrosis	13	9	22
	Livedo reticularis	1	0	1
	Night sweats	2	0	2
	Pain of skin	3	0	3
	Palmoplantar pustulosis	0	1	1
	Papule	0	1	1
	Petechiae	1	0	1
	Pityriasis rosea	0	1	1
	Pruritus	20	18	38
	Rash	8	13	21
	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	45	25	70
	Skin reaction	0	1	1
	Skin sensitisation	1	0	1
	Urticaria	8	7	15
	Urticaria papular	0	1	1
	Yellow skin	1	0	1
Social circumstances	Bedridden	2	0	2
	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	3	5	8
	Haemorrhage	1	0	1
	Hot flush	12	12	24
	Hypertension	33	10	43
	Hypertensive crisis	1	0	1
	Hypotension	16	7	23
	Hypovolaemic shock	2	0	2
	Lymphoedema	1	0	1
	Neurogenic shock	2	0	2
	Pallor	3	1	4
	Peripheral coldness	3	1	4
	Phlebitis	0	1	1

	Phlebitis superficial	2	1	3
	Thrombophlebitis	1	1	2
	Thrombophlebitis superficial	0	1	1
	Thrombosis	5	0	5
	Vasculitis	0	1	1
	Vasodilatation	1	1	2
	Vein disorder	1	0	1
	Vein rupture	1	0	1
Total		5591	3363	8.954