

Summary Tabulation 01.06.2021

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	41	11	52
	Leukocytosis	2	0	2
	Lymph node pain	2	4	6
	Lymphadenitis	0	1	1
	Lymphadenopathy	32	39	71
	Microangiopathic haemolytic anaemia	1	0	1
	Neutropenia	1	0	1
	Thrombocytopenia	7	4	11
Cardiac disorders	Angina pectoris	2	1	3
	Arrhythmia	4	1	5
	Atrial fibrillation	3	0	3
	Atrioventricular block	1	0	1
	Atrioventricular block complete	1	0	1
	Atrioventricular block second degree	1	0	1
	Bradycardia	9	1	10
	Bundle branch block left	1	0	1
	Cardiac arrest	11	0	11
	Cardiac disorder	4	0	4
	Cardiac failure	4	0	4
	Cardiac failure acute	1	0	1
	Cardio-respiratory arrest	4	0	4
	Cardiogenic shock	2	0	2
	Cardiomegaly	2	0	2
	Cardiomyopathy	1	0	1
	Cardiovascular disorder	63	17	80
	Coronary artery thrombosis	1	0	1
	Extrasystoles	1	0	1
	Myocarditis	2	0	2
	Nodal arrhythmia	1	0	1
	Palpitations	16	11	27
	Pericardial effusion	2	0	2
	Pericarditis	4	0	4
	Rhythm idioventricular	1	0	1
	Sinus tachycardia	1	0	1
	Stress cardiomyopathy	0	1	1

	Supraventricular tachycardia	1	0	1
	Tachyarrhythmia	2	0	2
	Tachycardia	31	18	49
Ear and labyrinth disorders	Deafness	2	0	2
	Deafness unilateral	1	0	1
	Dysacusis	1	0	1
	Ear discomfort	1	2	3
	Ear pain	6	3	9
	Endolymphatic hydrops	2	0	2
	Hypoacusis	1	1	2
	Meniere's disease	0	1	1
	Sudden hearing loss	1	0	1
	Tinnitus	10	4	14
	Vertigo	30	13	43
	Vertigo positional	0	2	2
	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
	Blepharospasm	1	0	1
	Blindness	2	0	2
	Diplopia	3	0	3
	Endocrine ophthalmopathy	0	1	1
	Eye haemorrhage	1	0	1
	Eye inflammation	1	0	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	1	3	4
	Ocular hyperaemia	1	1	2
	Photophobia	1	0	1
	Photopsia	1	1	2
	Retinal detachment	1	0	1
	Retinal pigment epitheliopathy	1	0	1
	Retinal vascular occlusion	1	0	1
	Retinal vein occlusion	1	0	1
	Retinal vein thrombosis	0	1	1
	Swelling of eyelid	1	0	1
	Vision blurred	7	5	12
	Visual field defect	3	0	3
	Visual impairment	8	3	11
	Vitreous floaters	1	1	2
Gastrointestinal disorders	Abdominal discomfort	2	7	9
	Abdominal distension	1	1	2

	Abdominal pain	15	12	27
	Abdominal pain upper	11	8	19
	Anal incontinence	1	1	2
	Aphthous ulcer	2	2	4
	Breath odour	2	0	2
	Colitis	1	0	1
	Constipation	1	1	2
	Diarrhoea	44	31	75
	Diarrhoea haemorrhagic	0	1	1
	Dry mouth	3	2	5
	Dyspepsia	2	3	5
	Dysphagia	6	2	8
	Enterocolitis haemorrhagic	1	0	1
	Faecal vomiting	1	0	1
	Faeces discoloured	2	0	2
	Flatulence	1	2	3
	Gastric dilatation	2	0	2
	Gastrointestinal disorder	4	1	5
	Gastrointestinal pain	4	2	6
	Gastrooesophageal 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	402	222	624
	Noninfective gingivitis	0	1	1
	Oral pruritus	0	1	1
	Pancreatitis	1	0	1
	Paraesthesia oral	5	5	10
	Parotid gland enlargement	1	1	2
	Rectal haemorrhage	1	1	2
	Retching	4	0	4
	Salivary gland pain	1	0	1
	Salivary hypersecretion	3	0	3
	Stomatitis	1	1	2
	Swollen tongue	6	4	10
	Tongue discolouration	0	1	1
	Tongue discomfort	1	0	1
	Tongue oedema	1	0	1
	Tooth disorder	0	1	1
	Vomiting	56	34	90
General disorders and administration site conditions	Application site oedema	1	0	1
	Asthenia	33	32	65
	Axillary pain	10	19	29
	Chest discomfort	11	2	13
	Chest pain	33	7	40

Chills	502	241	743
Condition aggravated	1	1	2
Crying	2	0	2
Death	19	0	19
Discomfort	2	0	2
Disease recurrence	1	0	1
Drug ineffective	6	1	7
Drug resistance	1	0	1
Exercise tolerance decreased	4	0	4
Extensive swelling of vaccinated limb	33	2	35
Face oedema	1	2	3
Facial pain	0	1	1
Fatigue	648	384	1 032
Feeling abnormal	10	8	18
Feeling cold	6	7	13
Feeling drunk	0	2	2
Feeling hot	6	16	22
Feeling of body temperature change	6	16	22
Foaming at mouth	1	0	1
Gait disturbance	2	0	2
Gait inability	1	3	4
General physical health deterioration	20	0	20
Hangover	1	1	2
Hunger	0	1	1
Hyperthermia	0	6	6
Hypothermia	3	1	4
Illness	1	3	4
Induration	0	1	1
Inflammation	3	5	8
Influenza like illness	70	61	131
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	3	1	4
Injection site oedema	0	2	2
Injection site pain	46	109	155
Injection site paraesthesia	0	1	1
Injection site pruritus	1	5	6
Injection site rash	0	3	3
Injection site reaction	330	161	491
Injection site swelling	10	29	39
Injection site warmth	5	15	20
Malaise	375	197	572
Multiple organ dysfunction syndrome	2	0	2

	Oedema	0	1	1
	Oedema peripheral	2	0	2
	Pain	13	16	29
	Peripheral swelling	39	60	99
	Pyrexia	480	370	850
	Screaming	0	1	1
	Secretion discharge	0	1	1
	Sensation of foreign body	2	0	2
	Sense of oppression	4	9	13
	Sluggishness	1	0	1
	Sudden death	25	0	25
	Swelling	4	8	12
	Swelling face	5	2	7
	Therapeutic response unexpected	1	0	1
	Thirst	3	3	6
	Vaccination failure	3	0	3
	Vaccination site discolouration	0	1	1
	Vaccination site discomfort	0	2	2
	Vaccination site erythema	1	8	9
	Vaccination site induration	1	2	3
	Vaccination site movement impairment	0	2	2
	Vaccination site pain	2	43	45
	Vaccination site pruritus	0	3	3
	Vaccination site reaction	0	5	5
	Vaccination site swelling	1	4	5
	Vaccination site warmth	0	3	3
Hepatobiliary disorders	Hepatic cytolysis	1	0	1
	Hepatic failure	1	0	1
	Hepatitis	2	1	3
	Liver disorder	8	0	8
Immune system disorders	Allergic reaction to excipient	0	1	1
	Anaphylactic reaction	30	4	34
	Anaphylactic shock	5	0	5
	Anaphylactoid reaction	1	0	1
	Autoimmune disorder	5	3	8
	Food allergy	1	0	1
	Hypersensitivity	19	8	27
Infections and infestations	Abscess	1	0	1
	Appendicitis	3	0	3
	Asymptomatic COVID-19	1	0	1
	Bronchitis	1	0	1
	COVID-19	74	21	95
	COVID-19 pneumonia	2	0	2
	Diverticulitis	0	1	1
	Ear infection	0	1	1
	Erysipelas	2	0	2
	Herpes ophthalmic	2	1	3
	Herpes simplex	1	0	1
	Herpes virus infection	1	1	2
	Herpes zoster	7	25	32

	Hordeolum	1	0	1
	Infection	1	0	1
	Influenza	3	19	22
	Injection site pustule	0	1	1
	Laryngitis	1	0	1
	Localised infection	1	0	1
	Nasopharyngitis	3	3	6
	Ophthalmic herpes zoster	1	1	2
	Oral fungal infection	1	0	1
	Oral herpes	5	0	5
	Parapharyngeal space infection	1	0	1
	Parotitis	0	1	1
	Pharyngitis	1	2	3
	Pneumonia	7	0	7
	Pneumonia bacterial	1	0	1
	Pyelonephritis	2	0	2
	Respiratory tract infection	2	0	2
	Rhinitis	3	2	5
	Rhinolaryngitis	0	1	1
	Scarlet fever	1	0	1
	Sepsis	2	0	2
	Septic shock	2	0	2
	Sinusitis	2	2	4
	Suspected COVID-19	1	0	1
	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	3	3
	Drug administered in wrong device	0	1	1
	Eschar	1	0	1
	Exposure via breast milk	0	1	1
	Facial bones fracture	1	0	1
	Fall	13	0	13
	Inappropriate schedule of product administration	0	2	2
	Incorrect dose administered	0	1	1
	Incorrect route of product administration	0	1	1
	Maternal exposure during pregnancy	0	1	1
	Muscle strain	0	3	3
	Nerve injury	1	0	1
	Off label use	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
	Bile output increased	1	0	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	12	4	16
	Blood pressure increased	10	2	12
	Blood test abnormal	1	0	1
	Blood urine present	1	0	1
	Body temperature fluctuation	1	0	1
	Body temperature increased	7	12	19
	Brain natriuretic peptide increased	1	0	1
	C-reactive protein increased	4	1	5
	Fibrin D dimer increased	7	0	7
	Gamma-glutamyltransferase increased	0	1	1
	Haemoglobin decreased	2	0	2
	Heart rate decreased	2	0	2
	Heart rate increased	9	4	13
	Heart rate irregular	1	1	2
	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 increased	1	0	1
	Oxygen saturation abnormal	1	0	1
	Oxygen saturation decreased	32	4	36
	PO2 decreased	1	0	1
	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	4	0	4
	Weight decreased	2	0	2
	White blood cell count decreased	1	0	1
Metabolism and nutrition disorders	Decreased appetite	18	10	28
	Dehydration	1	0	1
	Diabetic complication	1	0	1
	Fluid retention	1	1	2
	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	274	120	394
	Arthritis	3	2	5
	Axillary mass	1	0	1

	Back pain	13	15	28
	Bone pain	6	2	8
	Bursitis	1	0	1
	Groin pain	0	1	1
	Jaw disorder	0	1	1
	Joint range of motion decreased	0	1	1
	Joint stiffness	1	0	1
	Joint swelling	1	1	2
	Limb discomfort	11	3	14
	Mastication disorder	1	0	1
	Mobility decreased	0	1	1
	Muscle disorder	1	0	1
	Muscle spasms	3	3	6
	Muscle tightness	0	1	1
	Muscular weakness	5	10	15
	Musculoskeletal chest pain	0	2	2
	Musculoskeletal discomfort	1	2	3
	Musculoskeletal stiffness	23	72	95
	Myalgia	526	374	900
	Myosclerosis	0	1	1
	Neck pain	14	19	33
	Neuropathic muscular atrophy	1	0	1
	Pain in extremity	36	93	129
	Pain in jaw	1	1	2
	Posture abnormal	0	1	1
	SAPHO syndrome	0	1	1
	Spinal pain	1	1	2
	Tendonitis	1	0	1
	Torticollis	1	0	1
	Trismus	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Tumour thrombosis	1	0	1
Nervous system disorders	Ageusia	1	3	4
	Allodynia	1	0	1
	Altered state of consciousness	4	2	6
	Amnesia	1	0	1
	Anosmia	2	3	5
	Aphasia	6	1	7
	Balance disorder	10	2	12
	Bell's palsy	2	0	2
	Brain injury	1	0	1
	Brain oedema	1	0	1
	Burning sensation	6	5	11
	Carotid artery occlusion	2	0	2
	Carotid artery thrombosis	1	0	1
	Cerebral haemorrhage	2	0	2
	Cerebral infarction	1	0	1
	Cerebral ischaemia	2	0	2
	Cerebral thrombosis	3	0	3
	Cerebrovascular accident	17	0	17
	Circadian rhythm sleep disorder	0	1	1

Coma	4	0	4
Depressed level of consciousness	10	0	10
Disturbance in attention	2	3	5
Dizziness	50	34	84
Dysaesthesia	1	0	1
Dysgeusia	11	10	21
Dyspraxia	1	0	1
Dysstasia	1	1	2
Dystonia	1	0	1
Electric shock sensation	2	0	2
Encephalomalacia	1	0	1
Epilepsy	11	2	13
Facial nerve disorder	1	0	1
Facial paralysis	16	0	16
Facial paresis	12	0	12
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	635	447	1 082
Hemianaesthesia	2	0	2
Hemiparaesthesia	1	0	1
Hemiparesis	3	0	3
Hemiplegia	9	0	9
Hyperaesthesia	2	1	3
Hyperresponsive to stimuli	1	0	1
Hypersomnia	1	1	2
Hypertonia	1	0	1
Hypoaesthesia	10	15	25
Hyporesponsive to stimuli	1	0	1
Ischaemic cerebral infarction	1	0	1
Ischaemic stroke	3	0	3
Lethargy	1	0	1
Loss of consciousness	12	0	12
Memory impairment	2	0	2
Migraine	17	9	26
Migraine with aura	2	0	2
Monoplegia	2	0	2
Motor dysfunction	1	0	1
Muscle contractions involuntary	1	1	2
Nerve compression	1	0	1
Nervous system disorder	55	27	82
Neuralgia	2	0	2
Neuritis	1	0	1
Neuropathy peripheral	1	0	1
Noninfective encephalitis	1	0	1
Orthostatic intolerance	1	0	1

	Paraesthesia	15	27	42
	Paralysis	3	0	3
	Paresis	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	10	14	24
	Psychomotor hyperactivity	1	0	1
	Quadriparesis	1	0	1
	Sciatica	1	0	1
	Sedation	3	0	3
	Seizure	14	2	16
	Sensory disturbance	1	1	2
	Sleep deficit	1	0	1
	Somnolence	7	4	11
	Speech disorder	4	3	7
	Syncope	27	6	33
	Taste disorder	3	1	4
	Tension headache	0	1	1
	Thoracic outlet syndrome	1	0	1
	Transient ischaemic attack	3	0	3
	Tremor	10	5	15
	Trigeminal neuralgia	2	0	2
	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	6	2	8
	Anxiety	6	2	8
	Apathy	2	1	3
	Attention deficit hyperactivity disorder	1	0	1
	Aversion	0	1	1
	Confusional state	7	10	17
	Delirium	2	0	2
	Delusion	0	1	1
	Depressed mood	0	1	1
	Depression	1	0	1
	Depressive symptom	0	1	1
	Disorientation	2	0	2
	Hallucination	5	1	6
	Hallucination, visual	0	1	1
	Insomnia	21	9	30
	Irritability	1	0	1
	Middle insomnia	0	3	3
	Nightmare	2	0	2
	Poor quality sleep	1	4	5
	Restlessness	1	1	2
	Sleep disorder	3	2	5

	Staring	1	0	1
Renal and urinary disorders	Acute kidney injury	6	0	6
	Chromaturia	1	0	1
	Haematuria	1	1	2
	Incontinence	0	1	1
	Oliguria	1	0	1
	Polyuria	1	2	3
	Renal disorder	8	0	8
	Renal failure	3	0	3
	Renal pain	4	2	6
	Renal vein thrombosis	1	0	1
	Urinary retention	1	0	1
Reproductive system and breast disorders	Breast inflammation	1	0	1
	Breast pain	2	0	2
	Endometriosis	1	0	1
	Heavy menstrual bleeding	1	0	1
	Intermenstrual bleeding	0	1	1
	Menstrual disorder	1	0	1
	Oligomenorrhoea	1	0	1
	Pelvic pain	0	1	1
	Polymenorrhoea	1	0	1
	Suppressed lactation	1	0	1
	Vaginal haemorrhage	1	1	2
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1
	Acute respiratory failure	3	0	3
	Aphonia	0	1	1
	Asphyxia	1	0	1
	Asthma	2	1	3
	Asthma exercise induced	1	0	1
	Bradypnoea	1	0	1
	Bronchial disorder	1	0	1
	Bronchospasm	4	0	4
	Cheyne-Stokes respiration	1	0	1
	Cough	24	10	34
	Diaphragmalgia	0	1	1
	Dry throat	1	1	2
	Dysphonia	3	4	7
	Dyspnoea	60	12	72
	Dyspnoea exertional	4	1	5
	Epistaxis	2	9	11
	Haemoptysis	2	0	2
	Hyperventilation	3	1	4
	Hypoxia	1	0	1
	Laryngeal discomfort	0	1	1
	Laryngeal oedema	1	1	2
	Laryngospasm	1	0	1
	Lower respiratory tract congestion	1	0	1
	Lung infiltration	1	0	1
	Nasal congestion	1	2	3
	Nasal discomfort	0	1	1

Oropharyngeal discomfort	1	1	2
Oropharyngeal pain	10	14	24
Orthopnoea	1	0	1
Painful respiration	2	1	3
Pharyngeal paraesthesia	1	0	1
Pharyngeal swelling	4	3	7
Pleural effusion	2	0	2
Pleuritic pain	0	1	1
Pneumonia aspiration	2	0	2
Pneumonitis	1	0	1
Productive cough	4	1	5
Pulmonary arterial hypertension	1	0	1
Pulmonary embolism	26	1	27
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	72	29	101
Respiratory distress	3	0	3
Respiratory failure	5	0	5
Rhinitis allergic	1	0	1
Rhinorrhoea	8	6	14
Sinus pain	1	0	1
Sneezing	5	2	7
Stridor	1	0	1
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	3	3
Erythema	17	22	39
Hyperhidrosis	17	23	40
Livedo reticularis	1	0	1
Macule	0	1	1
Night sweats	3	2	5
Pain of skin	3	1	4
Palmoplantar pustulosis	0	1	1
Papule	0	1	1
Petechiae	1	2	3
Pityriasis rosea	0	1	1
Pruritus	25	22	47

	Rash	10	16	26
	Rash erythematous	2	9	11
	Rash macular	2	0	2
	Rash maculo-papular	1	0	1
	Rash papular	0	3	3
	Rash pruritic	2	0	2
	Scar pain	1	0	1
	Sensitive skin	3	3	6
	Skin burning sensation	1	0	1
	Skin discolouration	2	0	2
	Skin disorder	58	33	91
	Skin haemorrhage	0	1	1
	Skin reaction	0	1	1
	Skin sensitisation	1	0	1
	Urticaria	9	7	16
	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
	Interchange of vaccine products	0	1	1
	Resuscitation	1	0	1
Vascular disorders	Circulatory collapse	1	0	1
	Cyanosis	3	1	4
	Deep vein thrombosis	16	2	18
	Flushing	2	1	3
	Haematoma	4	5	9
	Haemorrhage	1	0	1
	Hot flush	14	12	26
	Hyperaemia	1	0	1
	Hypertension	38	13	51
	Hypertensive crisis	2	0	2
	Hypotension	17	8	25
	Hypovolaemic shock	2	0	2
	Lymphoedema	1	0	1
	Neurogenic shock	2	0	2
	Orthostatic hypotension	0	2	2
	Pallor	3	1	4
	Peripheral coldness	3	2	5
	Peripheral venous disease	1	0	1
	Phlebitis	0	2	2
	Phlebitis superficial	2	1	3
	Thrombophlebitis	1	1	2
	Thrombophlebitis superficial	0	1	1
	Thrombosis	9	0	9
	Vasculitis	0	1	1
	Vasodilatation	2	1	3
	Vein disorder	2	0	2
	Vein rupture	1	0	1
	Venous occlusion	1	0	1

	Venous thrombosis	0	1	1
	Venous thrombosis limb	1	0	1
Total		6887	4402	11 289