

Summary Tabulation 18.05.2021

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	34	11	45
	Leukocytosis	2	0	2
	Lymph node pain	1	3	4
	Lymphadenitis	0	1	1
	Lymphadenopathy	31	32	63
	Microangiopathic haemolytic anaemia	1	0	1
	Neutropenia	1	0	1
	Thrombocytopenia	7	4	11
Cardiac disorders	Angina pectoris	2	1	3
	Arrhythmia	3	1	4
	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	4	0	4
	Cardiogenic shock	2	0	2
	Cardiomegaly	2	0	2
	Cardiovascular disorder	59	17	76
	Coronary artery thrombosis	1	0	1
	Extrasystoles	1	0	1
	Myocarditis	2	0	2
	Palpitations	15	11	26
	Pericardial effusion	2	0	2
	Pericarditis	3	0	3
	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	17	46
	Ear and labyrinth disorders	Deafness	1	0
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	8	3	11
	Vertigo	24	11	35
	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 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	3	3
	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	6	3	9
	Visual field defect	3	0	3
	Visual impairment	8	3	11
	Vitreous floaters	1	1	2
Gastrointestinal disorders	Abdominal discomfort	1	7	8
	Abdominal distension	1	1	2
	Abdominal pain	12	12	24
	Abdominal pain upper	11	4	15
	Anal incontinence	1	1	2
	Aphthous ulcer	2	2	4
	Breath odour	2	0	2
	Constipation	1	1	2
	Diarrhoea	37	26	63
	Diarrhoea haemorrhagic	0	1	1

	Dry mouth	3	2	5
	Dyspepsia	1	2	3
	Dysphagia	5	2	7
	Faecal vomiting	1	0	1
	Faeces discoloured	2	0	2
	Flatulence	1	2	3
	Gastric dilatation	2	0	2
	Gastrointestinal disorder	3	1	4
	Gastrointestinal pain	4	1	5
	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	356	207	563
	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
	Vomiting	48	27	75
General disorders and administration site conditions	Application site oedema	1	0	1
	Asthenia	30	27	57
	Axillary pain	8	14	22
	Chest discomfort	11	2	13
	Chest pain	28	5	33
	Chills	461	222	683
	Condition aggravated	1	1	2
	Crying	2	0	2
	Death	15	0	15
	Discomfort	2	0	2
	Drug ineffective	5	0	5
	Drug resistance	1	0	1
	Exercise tolerance decreased	4	0	4
	Extensive swelling of vaccinated limb	25	1	26
	Face oedema	1	2	3
	Facial pain	0	1	1
	Fatigue	578	349	927

Feeling abnormal	8	5	13
Feeling cold	7	6	13
Feeling drunk	0	2	2
Feeling hot	5	15	20
Feeling of body temperature change	5	12	17
Gait disturbance	2	0	2
Gait inability	1	3	4
General physical health deterioration	19	0	19
Hangover	1	1	2
Hunger	0	1	1
Hyperthermia	0	6	6
Hypothermia	3	1	4
Illness	1	1	2
Induration	0	1	1
Inflammation	3	4	7
Influenza like illness	67	49	116
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	43	108	151
Injection site paraesthesia	0	1	1
Injection site pruritus	1	5	6
Injection site rash	0	3	3
Injection site reaction	290	157	447
Injection site swelling	10	28	38
Injection site warmth	5	15	20
Malaise	336	185	521
Multiple organ dysfunction syndrome	2	0	2
Oedema	0	1	1
Oedema peripheral	2	0	2
Pain	10	12	22
Peripheral swelling	38	58	96
Pyrexia	431	337	768
Secretion discharge	0	1	1
Sensation of foreign body	2	0	2
Sense of oppression	3	9	12
Sudden death	24	0	24
Swelling	2	7	9
Swelling face	5	2	7
Therapeutic response unexpected	1	0	1
Thirst	3	2	5
Vaccination failure	3	0	3

	Vaccination site discolouration	0	1	1
	Vaccination site discomfort	0	1	1
	Vaccination site erythema	1	5	6
	Vaccination site induration	1	1	2
	Vaccination site movement impairment	0	1	1
	Vaccination site pain	2	28	30
	Vaccination site pruritus	0	2	2
	Vaccination site reaction	0	2	2
	Vaccination site swelling	1	2	3
	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	29	4	33
	Anaphylactic shock	5	0	5
	Anaphylactoid reaction	1	0	1
	Autoimmune disorder	5	3	8
	Food allergy	1	0	1
	Hypersensitivity	18	8	26
Infections and infestations	Abscess	1	0	1
	Appendicitis	3	0	3
	Asymptomatic COVID-19	1	0	1
	Bronchitis	1	0	1
	COVID-19	48	16	64
	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	3	13	16
	Hordeolum	1	0	1
	Infection	1	0	1
	Influenza	2	14	16
	Laryngitis	1	0	1
	Localised infection	1	0	1
	Nasopharyngitis	3	3	6
	Ophthalmic herpes zoster	1	1	2
	Oral herpes	5	0	5
	Parapharyngeal space infection	1	0	1
	Pharyngitis	1	2	3
	Pneumonia	6	0	6
	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	13	0	13
	Inappropriate schedule of product administration	0	1	1
	Incorrect dose administered	0	1	1
	Incorrect route of product administration	0	1	1
	Muscle strain	0	1	1
	Nerve injury	1	0	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	11	4	15
	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	10	17
	C-reactive protein increased	3	1	4
	Fibrin D dimer increased	6	0	6
	Gamma-glutamyltransferase increased	0	1	1
	Haemoglobin decreased	1	0	1
	Heart rate decreased	2	0	2
	Heart rate increased	8	3	11
	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 increased	1	0	1
	Oxygen saturation abnormal	1	0	1
	Oxygen saturation decreased	29	4	33

	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	15	9	24
	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	229	111	340
	Arthritis	3	2	5
	Axillary mass	1	0	1
	Back pain	13	10	23
	Bone pain	6	2	8
	Groin pain	0	1	1
	Jaw disorder	0	1	1
	Joint stiffness	1	0	1
	Joint swelling	1	1	2
	Limb discomfort	11	2	13
	Mastication disorder	1	0	1
	Muscle disorder	1	0	1
	Muscle spasms	1	2	3
	Muscular weakness	4	8	12
	Musculoskeletal chest pain	0	2	2
	Musculoskeletal discomfort	0	1	1
	Musculoskeletal stiffness	21	63	84
	Myalgia	469	337	806
	Myosclerosis	0	1	1
	Neck pain	13	15	28
	Neuropathic muscular atrophy	1	0	1
	Pain in extremity	35	83	118
	Pain in jaw	1	0	1
	Posture abnormal	0	1	1
	SAPHO syndrome	0	1	1
	Spinal pain	1	1	2
	Tendonitis	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Tumour thrombosis	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	10	2	12
Bell's palsy	2	0	2
Brain injury	1	0	1
Burning sensation	6	4	10
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	16	0	16
Coma	2	0	2
Depressed level of consciousness	10	0	10
Disturbance in attention	2	3	5
Dizziness	44	27	71
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
Epilepsy	9	1	10
Facial nerve disorder	1	0	1
Facial paralysis	16	0	16
Facial paresis	11	0	11
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	580	401	981
Hemianaesthesia	2	0	2
Hemiparaesthesia	1	0	1
Hemiparesis	1	0	1
Hemiplegia	8	0	8
Hyperaesthesia	2	0	2
Hyperresponsive to stimuli	1	0	1
Hypersomnia	1	1	2
Hypertonia	1	0	1
Hypoaesthesia	9	13	22
Hyporesponsive to stimuli	1	0	1
Ischaemic cerebral infarction	1	0	1
Ischaemic stroke	3	0	3
Lethargy	1	0	1
Loss of consciousness	10	0	10

	Memory impairment	2	0	2
	Migraine	17	7	24
	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	48	26	74
	Neuralgia	2	0	2
	Neuritis	1	0	1
	Neuropathy peripheral	1	0	1
	Noninfective encephalitis	1	0	1
	Orthostatic intolerance	1	0	1
	Paraesthesia	12	23	35
	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	9	14	23
	Psychomotor hyperactivity	1	0	1
	Sedation	3	0	3
	Seizure	12	2	14
	Sensory disturbance	1	1	2
	Sleep deficit	1	0	1
	Somnolence	7	3	10
	Speech disorder	4	3	7
	Syncope	26	5	31
	Taste disorder	3	1	4
	Thoracic outlet syndrome	1	0	1
	Transient ischaemic attack	1	0	1
	Tremor	9	4	13
	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	5	2	7
	Anxiety	6	2	8
	Apathy	2	1	3
	Attention deficit hyperactivity disorder	1	0	1
	Aversion	0	1	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	8	26
	Irritability	1	0	1
	Middle insomnia	0	2	2
	Nightmare	1	0	1
	Poor quality sleep	1	3	4
	Restlessness	1	1	2
	Sleep disorder	3	2	5
	Staring	1	0	1
Renal and urinary disorders	Acute kidney injury	5	0	5
	Chromaturia	1	0	1
	Haematuria	1	1	2
	Polyuria	1	1	2
	Renal disorder	8	0	8
	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	1	2
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1
	Acute respiratory failure	3	0	3
	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	19	10	29
	Dry throat	1	1	2
	Dysphonia	3	3	6
	Dyspnoea	54	10	64
	Dyspnoea exertional	4	0	4
	Epistaxis	2	8	10
	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	2	3
	Nasal discomfort	0	1	1
	Oropharyngeal pain	9	14	23
	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	2	1	3
Pulmonary arterial hypertension	1	0	1
Pulmonary embolism	22	0	22
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	70	29	99
Respiratory distress	3	0	3
Respiratory failure	2	0	2
Rhinitis allergic	1	0	1
Rhinorrhoea	7	6	13
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	3	3
Erythema	17	20	37
Hyperhidrosis	13	16	29
Livedo reticularis	1	0	1
Night sweats	2	1	3
Pain of skin	3	1	4
Palmoplantar pustulosis	0	1	1
Papule	0	1	1
Petechiae	1	1	2
Pityriasis rosea	0	1	1
Pruritus	22	20	42
Rash	9	15	24
Rash erythematous	2	9	11
Rash macular	2	0	2
Rash maculo-papular	1	0	1
Rash papular	0	2	2
Rash pruritic	2	0	2
Scar pain	1	0	1

	Sensitive skin	3	3	6
	Skin burning sensation	1	0	1
	Skin discolouration	1	0	1
	Skin disorder	52	28	80
	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
	Resuscitation	1	0	1
Vascular disorders	Cyanosis	3	1	4
	Deep vein thrombosis	11	2	13
	Flushing	2	1	3
	Haematoma	4	5	9
	Haemorrhage	1	0	1
	Hot flush	13	12	25
	Hypertension	35	11	46
	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
	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	8	0	8
	Vasculitis	0	1	1
	Vasodilatation	2	1	3
	Vein disorder	1	0	1
	Vein rupture	1	0	1
	Venous occlusion	1	0	1
	Venous thrombosis	0	1	1
Total		6148	3938	10.086

Rows 1 - 578 (All Rows)