

## Summary Tabulation 04.05.2021

Active Substance (High Level)		COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)		
Reaction SOC	Reaction PT	Serious	Non Serious	Total
Blood and lymphatic system disorders	Coagulopathy	32	15	47
	Coombs negative haemolytic anaemia	1	0	1
	Disseminated intravascular coagulation	1	0	1
	Immune thrombocytopenia	1	0	1
	Leukocytosis	1	0	1
	Leukopenia	1	0	1
	Lymphadenopathy	5	2	7
	Lymphopenia	1	0	1
	Neutropenia	2	1	3
	Thrombocytopenia	13	4	17
Cardiac disorders	Angina pectoris	2	0	2
	Arrhythmia	4	1	5
	Bradycardia	1	1	2
	Cardiac arrest	2	0	2
	Cardiac failure	2	0	2
	Cardiovascular disorder	36	6	42
	Myocardial infarction	2	0	2
	Palpitations	28	3	31
	Sinus tachycardia	1	0	1
	Tachycardia	24	3	27
Ear and labyrinth disorders	Deafness	1	2	3
	Deafness unilateral	3	1	4
	Ear congestion	0	1	1
	Ear discomfort	3	0	3
	Ear pain	9	2	11
	Hyperacusis	3	0	3
	Sudden hearing loss	0	1	1
	Tinnitus	4	1	5
	Vertigo	21	1	22
Endocrine disorders	Adrenocortical insufficiency acute	1	0	1
	Goitre	1	0	1
Eye disorders	Amaurosis fugax	1	1	2
	Asthenopia	1	0	1
	Blindness	2	1	3
	Blindness unilateral	4	0	4
	Conjunctival haemorrhage	1	1	2
	Eye haemorrhage	1	1	2

	Eye irritation	1	0	1
	Eye pain	1	2	3
	Eye swelling	1	0	1
	Macular oedema	1	0	1
	Miosis	1	0	1
	Mydriasis	1	0	1
	Ocular discomfort	1	0	1
	Papilloedema	1	0	1
	Photophobia	5	0	5
	Retinal artery thrombosis	2	0	2
	Retinal ischaemia	1	0	1
	Retinal vascular thrombosis	0	1	1
	Retinal vein thrombosis	2	0	2
	Vision blurred	10	0	10
	Visual impairment	10	2	12
	Visual snow syndrome	1	0	1
Gastrointestinal disorders	Abdominal discomfort	3	0	3
	Abdominal distension	1	0	1
	Abdominal pain	16	2	18
	Abdominal pain upper	13	1	14
	Aphthous ulcer	0	1	1
	Colitis ischaemic	2	0	2
	Colitis ulcerative	1	0	1
	Constipation	1	0	1
	Crohn's disease	1	0	1
	Diarrhoea	37	1	38
	Diarrhoea haemorrhagic	0	1	1
	Dry mouth	3	0	3
	Dyspepsia	2	0	2
	Dysphagia	0	1	1
	Eructation	1	0	1
	Flatulence	1	0	1
	Gastrointestinal disorder	3	0	3
	Gastrointestinal pain	1	0	1
	Gastrooesophageal reflux disease	1	0	1
	Gingival bleeding	1	0	1
	Glossodynia	1	0	1
	Haemorrhoidal haemorrhage	1	0	1
	Haemorrhoids thrombosed	1	0	1
	Hypoaesthesia oral	0	1	1
	Intestinal congestion	1	0	1
	Intestinal infarction	1	0	1
	Intestinal ischaemia	2	0	2
	Lip pain	1	0	1
	Lip swelling	0	1	1
	Mouth haemorrhage	0	1	1
	Nausea	576	37	613
	Oesophageal spasm	1	0	1
	Oral discomfort	1	0	1
	Paraesthesia oral	3	2	5

	Rectal haemorrhage	0	1	1
	Regurgitation	1	0	1
	Retching	2	0	2
	Splanchnic hypoperfusion	1	0	1
	Thrombosis mesenteric vessel	1	0	1
	Vomiting	64	5	69
General disorders and administration site conditions	Adverse drug reaction	3	0	3
	Adverse event	1	0	1
	Application site joint warmth	1	0	1
	Asthenia	29	0	29
	Axillary pain	2	1	3
	Chest discomfort	5	1	6
	Chest pain	15	3	18
	Chills	1059	69	1.128
	Condition aggravated	2	0	2
	Death	4	0	4
	Exercise tolerance decreased	1	0	1
	Extensive swelling of vaccinated limb	52	3	55
	Face oedema	2	0	2
	Facial pain	0	1	1
	Fatigue	1023	67	1.090
	Feeling abnormal	13	2	15
	Feeling cold	26	2	28
	Feeling drunk	0	1	1
	Feeling hot	14	2	16
	Feeling of body temperature change	13	2	15
	Gait disturbance	1	0	1
	Gait inability	1	0	1
	General physical health deterioration	4	0	4
	Hyperpyrexia	0	1	1
	Hyperthermia	2	1	3
	Hypothermia	2	0	2
	Induration	2	0	2
	Influenza like illness	110	9	119
	Injected limb mobility decreased	1	0	1
	Injection site discomfort	2	0	2
	Injection site erythema	15	0	15
	Injection site haematoma	2	0	2
	Injection site hypoaesthesia	1	0	1
	Injection site induration	6	0	6
	Injection site inflammation	1	0	1
	Injection site movement impairment	1	0	1
	Injection site necrosis	1	0	1
	Injection site oedema	1	0	1
	Injection site pain	89	3	92
	Injection site paraesthesia	1	0	1
	Injection site phlebitis	0	1	1
	Injection site rash	1	0	1
Injection site reaction	514	37	551	
Injection site swelling	16	0	16	

	Injection site warmth	10	0	10
	Local reaction	1	0	1
	Malaise	562	48	610
	Multiple organ dysfunction syndrome	1	0	1
	No adverse event	1	0	1
	Oedema	1	0	1
	Oedema peripheral	1	0	1
	Pain	14	7	21
	Peripheral swelling	56	4	60
	Pyrexia	1051	72	1.123
	Secretion discharge	1	0	1
	Sudden death	5	0	5
	Swelling	2	2	4
	Swelling face	1	0	1
	Thirst	2	0	2
	Tissue infiltration	0	1	1
	Unevaluable event	1	0	1
	Vaccination site erythema	1	0	1
	Vaccination site haematoma	1	0	1
	Vaccination site movement impairment	1	0	1
	Vaccination site pain	1	0	1
Hepatobiliary disorders	Gallbladder necrosis	1	0	1
	Hepatic failure	1	0	1
	Hepatic steatosis	1	0	1
	Hyperbilirubinaemia	1	0	1
	Liver disorder	1	0	1
	Portal vein occlusion	1	0	1
	Venoocclusive liver disease	1	0	1
Immune system disorders	Anaphylactic reaction	5	3	8
	Autoimmune disorder	4	0	4
	Hypersensitivity	26	10	36
Infections and infestations	COVID-19	17	2	19
	Conjunctivitis viral	0	1	1
	Cystitis	1	0	1
	Diverticulitis	1	0	1
	Erysipelas	0	1	1
	Herpes zoster	0	1	1
	Influenza	8	5	13
	Laryngitis	1	0	1
	Lymphangitis	0	1	1
	Nasopharyngitis	3	1	4
	Oral herpes	1	0	1
	Pneumonia	1	0	1
	Sepsis	2	0	2
	Septic shock	1	0	1
	Streptococcal infection	1	0	1
	Subcutaneous abscess	0	1	1
	Tooth abscess	1	0	1
	Urinary tract infection	2	0	2
Injury, poisoning and procedural complications	Contusion	6	3	9

	Exposure during pregnancy	0	1	1
	Fall	5	1	6
	Head injury	1	0	1
	Incorrect route of product administration	1	1	2
	Kidney rupture	1	0	1
	Maternal exposure during breast feeding	1	0	1
	Medication error	1	2	3
	Off label use	0	1	1
	Venous injury	0	1	1
Investigations	Babinski reflex test	1	0	1
	Blood bilirubin increased	1	0	1
	Blood pressure decreased	8	0	8
	Blood pressure increased	3	1	4
	Body temperature decreased	1	0	1
	Body temperature increased	3	0	3
	C-reactive protein increased	2	0	2
	Fibrin D dimer increased	4	0	4
	General physical condition abnormal	2	0	2
	Haematocrit decreased	1	0	1
	Heart rate increased	13	4	17
	Heparin-induced thrombocytopenia test	1	0	1
	Interleukin level increased	1	0	1
	Liver function test abnormal	1	0	1
	Oxygen saturation decreased	3	0	3
	Platelet count decreased	3	0	3
	Platelet count increased	1	0	1
	Procalcitonin increased	1	0	1
	Red blood cell count decreased	1	0	1
	Red blood cell sedimentation rate increased	1	0	1
	Respiratory rate decreased	0	1	1
	Troponin T increased	1	0	1
	Troponin increased	2	0	2
	Weight decreased	2	0	2
Metabolism and nutrition disorders	Decreased appetite	48	4	52
	Gout	1	0	1
	Hypoglycaemia	1	0	1
	Lactic acidosis	2	0	2
Musculoskeletal and connective tissue disorders	Arthralgia	432	31	463
	Arthritis	4	0	4
	Back pain	23	4	27
	Bone pain	2	0	2
	Fibromyalgia	1	0	1
	Joint stiffness	0	1	1
	Limb discomfort	8	1	9
	Muscle spasms	11	0	11
	Muscle swelling	1	0	1
	Muscle twitching	1	0	1
	Muscular weakness	9	3	12
	Musculoskeletal stiffness	53	1	54
	Myalgia	870	66	936

	Myosclerosis	1	0	1
	Neck pain	12	1	13
	Osteoarthritis	1	0	1
	Pain in extremity	59	7	66
	Spinal deformity	0	1	1
	Spinal pain	0	1	1
Nervous system disorders	Ageusia	3	0	3
	Altered state of consciousness	2	1	3
	Amnesia	2	0	2
	Anosmia	1	0	1
	Aphasia	3	0	3
	Areflexia	1	0	1
	Balance disorder	4	1	5
	Bell's palsy	1	0	1
	Burning sensation	1	0	1
	Carotid artery thrombosis	1	0	1
	Cerebellar stroke	1	0	1
	Cerebral haemorrhage	3	0	3
	Cerebral infarction	2	0	2
	Cerebral thrombosis	2	0	2
	Cerebrovascular accident	5	0	5
	Depressed level of consciousness	3	0	3
	Disturbance in attention	7	1	8
	Dizziness	36	4	40
	Dizziness postural	1	0	1
	Dysarthria	3	0	3
	Dysgeusia	3	1	4
	Dysstasia	0	1	1
	Facial paralysis	6	0	6
	Formication	0	1	1
	Guillain-Barre syndrome	1	0	1
	Head discomfort	2	2	4
	Headache	1054	80	1.134
	Hemiparaesthesia	0	1	1
	Hemiparesis	1	0	1
	Hemiplegia	4	0	4
	Hyperaesthesia	4	0	4
	Hypoaesthesia	6	5	11
	Ischaemic stroke	1	0	1
	Loss of consciousness	2	1	3
	Memory impairment	2	0	2
	Meningism	0	1	1
	Migraine	20	0	20
	Monoplegia	1	0	1
	Motor dysfunction	1	0	1
	Muscle contractions involuntary	1	0	1
	Nervous system disorder	24	6	30
	Neuralgia	1	0	1
	Neuropathy peripheral	1	0	1
	Pachymeningitis	1	0	1

	Paraesthesia	10	2	12
	Presyncope	0	1	1
	Restless legs syndrome	3	0	3
	Seizure	14	6	20
	Sensory loss	0	1	1
	Somnolence	8	1	9
	Speech disorder	2	0	2
	Spinal cord ischaemia	1	0	1
	Syncope	13	4	17
	Taste disorder	2	1	3
	Transient ischaemic attack	2	0	2
	Tremor	15	2	17
	Unresponsive to stimuli	2	0	2
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	2	0	2
	Foetal death	1	0	1
	Preterm premature rupture of membranes	1	0	1
Product issues	Oversensing	1	0	1
Psychiatric disorders	Agitation	4	0	4
	Anxiety	2	1	3
	Apathy	1	0	1
	Confusional state	9	0	9
	Daydreaming	1	0	1
	Delusion	0	1	1
	Depressed mood	0	1	1
	Disorientation	1	0	1
	Dissociation	0	1	1
	Eating disorder	1	0	1
	Hallucination	1	1	2
	Hallucination, visual	1	0	1
	Initial insomnia	1	0	1
	Insomnia	23	1	24
	Nightmare	1	0	1
	Phonophobia	1	0	1
	Restlessness	3	0	3
	Stress	1	0	1
Renal and urinary disorders	Calculus urinary	1	0	1
	Chromaturia	1	0	1
	Haematuria	1	0	1
	Hydronephrosis	1	0	1
	Polyuria	1	0	1
	Renal colic	1	0	1
	Renal disorder	7	0	7
	Renal failure	1	0	1
	Renal pain	2	0	2
	Renal tubular disorder	1	0	1
	Renal vascular thrombosis	1	0	1
	Urge incontinence	1	0	1
	Urinary incontinence	2	0	2
Reproductive system and breast disorders	Amenorrhoea	1	0	1
	Breast cyst	1	0	1

	Breast inflammation	1	0	1
	Breast pain	2	0	2
	Dysmenorrhoea	1	0	1
	Ejaculation disorder	0	1	1
	Erectile dysfunction	1	0	1
	Heavy menstrual bleeding	2	0	2
	Menstrual disorder	2	0	2
	Vaginal haemorrhage	2	0	2
	Varicose veins pelvic	1	0	1
	Vulval haematoma	0	1	1
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1
	Apparent life threatening event	1	0	1
	Asthma	2	0	2
	Choking sensation	1	0	1
	Chronic obstructive pulmonary disease	1	0	1
	Cough	18	0	18
	Dysphonia	2	0	2
	Dyspnoea	39	1	40
	Dyspnoea exertional	4	0	4
	Epistaxis	8	1	9
	Hyperventilation	4	0	4
	Lung disorder	2	0	2
	Nasal congestion	2	0	2
	Oropharyngeal pain	8	1	9
	Painful respiration	1	0	1
	Pharyngeal paraesthesia	0	1	1
	Pharyngeal swelling	1	0	1
	Pleural effusion	2	0	2
	Productive cough	1	0	1
	Pulmonary embolism	13	0	13
	Pulmonary oedema	1	0	1
	Pulmonary pain	1	0	1
	Rales	1	0	1
	Respiratory disorder	76	11	87
	Respiratory distress	2	0	2
	Rhinorrhoea	2	1	3
	Sneezing	1	0	1
	Tachypnoea	1	0	1
	Throat irritation	1	0	1
	Wheezing	2	0	2
Skin and subcutaneous tissue disorders	Angioedema	1	1	2
	Blister	1	0	1
	Cold sweat	1	1	2
	Dermatitis allergic	1	0	1
	Eczema	1	0	1
	Erythema	6	0	6
	Erythema multiforme	0	1	1
	Hyperhidrosis	50	2	52
	Miliaria	2	0	2
	Night sweats	1	1	2



	Pain of skin	8	0	8
	Petechiae	3	1	4
	Photosensitivity reaction	2	0	2
	Pruritus	9	1	10
	Purpura	1	0	1
	Rash	3	1	4
	Rash erythematous	4	0	4
	Rash papular	0	1	1
	Rash pruritic	1	1	2
	Sensitive skin	3	0	3
	Skin disorder	48	12	60
	Skin lesion inflammation	1	0	1
	Skin mass	1	0	1
	Skin odour abnormal	1	0	1
	Urticaria	3	3	6
Social circumstances	Impaired work ability	1	0	1
	Walking disability	1	0	1
Surgical and medical procedures	Bed rest	1	0	1
	Dialysis	1	0	1
	Explorative laparotomy	1	0	1
Vascular disorders	Arterial thrombosis	1	0	1
	Arteriosclerosis	0	1	1
	Bloody discharge	1	0	1
	Cyanosis	2	2	4
	Deep vein thrombosis	9	1	10
	Flushing	1	0	1
	Giant cell arteritis	1	0	1
	Haematoma	3	3	6
	Haemodynamic instability	1	0	1
	Haemorrhage	1	0	1
	Hot flush	8	0	8
	Hypertension	13	2	15
	Hypertensive crisis	1	0	1
	Hypotension	14	2	16
	Hypovolaemic shock	1	0	1
	Ischaemia	1	0	1
	Jugular vein thrombosis	1	0	1
	Pallor	1	0	1
	Pelvic venous thrombosis	0	1	1
	Peripheral coldness	2	1	3
	Peripheral ischaemia	1	0	1
	Periphlebitis	0	1	1
	Phlebitis	2	2	4
	Phlebitis superficial	0	1	1
	Thrombophlebitis	1	0	1
	Thrombophlebitis superficial	2	1	3
	Thrombosis	6	3	9
	Varicose vein	1	0	1
	Vascular pain	0	1	1
	Vascular rupture	1	0	1

	Vasodilatation	1	1	2
	Venous aneurysm	0	1	1
	Venous thrombosis	3	1	4
	Venous thrombosis limb	0	1	1
<b>Total</b>		<b>9266</b>	<b>812</b>	<b>10.078</b>