

### Summary Tabulation 10-05-2021

Active Substance (High Level)	COVID-19 VACCINE ASTRAZENECA (CHAD0X1 NCOV-19)			
Reaction SOC	Reaction PT	Serious	Non Serious	Total
Blood and lymphatic system disorders	Anaemia	2	1	3
	Autoimmune haemolytic anaemia	1	0	1
	Coagulopathy	40	21	61
	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
	Necrotic lymphadenopathy	0	1	1
	Neutropenia	3	1	4
	Splenic embolism	1	0	1
	Splenic infarction	1	0	1
	Thrombocytopenia	19	5	24
Cardiac disorders	Acute cardiac event	1	0	1
	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	37	6	43
	Myocardial depression	1	0	1
	Myocardial infarction	2	0	2
	Palpitations	30	3	33
	Pericarditis	1	0	1
	Sinus tachycardia	1	0	1
	Tachycardia	25	3	28
Ear and labyrinth disorders	Deafness	1	2	3
	Deafness unilateral	4	1	5
	Ear congestion	0	2	2
	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	3	24

Endocrine disorders	Adrenocortical insufficiency acute	1	0	1
	Goitre	1	0	1
Eye disorders	Amaurosis fugax	1	1	2
	Asthenopia	2	0	2
	Blindness	3	1	4
	Blindness unilateral	4	0	4
	Conjunctival haemorrhage	1	1	2
	Eye haemorrhage	1	2	3
	Eye irritation	1	0	1
	Eye pain	3	2	5
	Eye swelling	2	0	2
	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
	Photopsia	1	0	1
	Retinal artery thrombosis	2	0	2
	Retinal ischaemia	1	0	1
	Retinal vascular thrombosis	0	1	1
	Retinal vein thrombosis	3	0	3
	Uveitis	1	0	1
	Vision blurred	11	1	12
	Visual field defect	1	0	1
	Visual impairment	12	3	15
	Visual snow syndrome	1	0	1
Gastrointestinal disorders	Abdominal discomfort	3	0	3
	Abdominal distension	1	0	1
	Abdominal pain	21	4	25
	Abdominal pain upper	14	1	15
	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	40	1	41
	Diarrhoea haemorrhagic	0	1	1
	Dry mouth	3	0	3
	Dyspepsia	2	0	2
	Dysphagia	0	1	1
	Eruption	1	0	1
	Faeces soft	1	0	1
	Flatulence	1	0	1
	Gastrointestinal disorder	4	0	4
	Gastrointestinal pain	1	0	1
	Gastrooesophageal reflux disease	1	0	1
	Gingival bleeding	1	0	1
	Glossodynna	1	0	1
	Haemorrhoidal haemorrhage	1	0	1

Haemorrhoids thrombosed	1	1	2
Hypoesthesia oral	0	1	1
Intestinal congestion	1	0	1
Intestinal infarction	1	0	1
Intestinal ischaemia	3	0	3
Lip pain	1	0	1
Lip swelling	0	1	1
Melaena	1	0	1
Mesenteric vein thrombosis	1	0	1
Mouth haemorrhage	0	1	1
Nausea	607	37	644
Oesophageal spasm	1	0	1
Oral discomfort	1	0	1
Paraesthesia oral	3	2	5
Rectal haemorrhage	1	2	3
Regurgitation	1	0	1
Retching	2	0	2
Splanchnic hypoperfusion	1	0	1
Swollen tongue	1	0	1
Thrombosis mesenteric vessel	1	0	1
Vomiting	66	5	71
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	30	0	30
Axillary pain	2	1	3
Chest discomfort	5	1	6
Chest pain	17	4	21
Chills	1101	70	1 171
Condition aggravated	2	0	2
Death	8	0	8
Exercise tolerance decreased	1	0	1
Extensive swelling of vaccinated limb	57	5	62
Face oedema	2	0	2
Facial pain	0	1	1
Fatigue	1066	71	1 137
Feeling abnormal	14	2	16
Feeling cold	26	3	29
Feeling drunk	0	1	1
Feeling hot	15	2	17
Feeling of body temperature change	13	2	15
Gait disturbance	1	0	1
Gait inability	1	0	1
General physical health deterioration	5	0	5
Hyperpyrexia	0	1	1
Hyperthermia	2	1	3
Hypothermia	2	0	2
Induration	2	0	2
Inflammation	1	0	1
Influenza like illness	115	9	124

	Injected limb mobility decreased	1	0	1
	Injection site discomfort	3	0	3
	Injection site erythema	15	0	15
	Injection site haematoma	2	0	2
	Injection site hypoesthesia	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	93	3	96
	Injection site paraesthesia	1	0	1
	Injection site phlebitis	0	1	1
	Injection site rash	1	0	1
	Injection site reaction	527	41	568
	Injection site swelling	16	0	16
	Injection site warmth	10	0	10
	Local reaction	1	0	1
	Malaise	589	50	639
	Multiple organ dysfunction syndrome	1	0	1
	No adverse event	1	0	1
	Oedema	1	0	1
	Oedema peripheral	2	0	2
	Pain	16	8	24
	Peripheral swelling	58	4	62
	Pyrexia	1094	73	1 167
	Secretion discharge	1	0	1
	Sudden death	5	0	5
	Swelling	3	2	5
	Swelling face	1	0	1
	Tenderness	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	2	0	2
	Portal vein occlusion	1	0	1
	Portal vein thrombosis	2	0	2
	Venoocclusive liver disease	1	0	1
Immune system disorders	Anaphylactic reaction	5	3	8
	Autoimmune disorder	5	0	5
	Hypersensitivity	26	10	36
Infections and infestations	COVID-19	23	3	26

	Chronic sinusitis	1	0	1
	Conjunctivitis viral	0	1	1
	Cystitis	1	0	1
	Diverticulitis	1	0	1
	Encephalitis	1	0	1
	Erysipelas	0	1	1
	Herpes zoster	0	2	2
	Influenza	8	5	13
	Laryngitis	1	0	1
	Lymphangitis	0	1	1
	Nasopharyngitis	4	1	5
	Oral herpes	1	0	1
	Pneumonia	1	0	1
	Sepsis	2	0	2
	Septic shock	2	0	2
	Streptococcal infection	1	0	1
	Subcutaneous abscess	0	1	1
	Tooth abscess	1	0	1
	Urinary tract infection	2	0	2
	Vestibular neuritis	1	0	1
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
	Vasoplegia syndrome	1	0	1
	Venous injury	0	1	1
Investigations	Anti-platelet antibody	1	0	1
	Babinski reflex test	1	0	1
	Blood albumin decreased	1	0	1
	Blood bilirubin increased	1	0	1
	Blood fibrinogen decreased	2	0	2
	Blood pressure decreased	8	0	8
	Blood pressure increased	3	1	4
	Body temperature decreased	1	0	1
	Body temperature increased	4	0	4
	C-reactive protein increased	6	0	6
	Capillary nail refill test abnormal	1	0	1
	Ejection fraction decreased	1	0	1
	Fibrin D dimer increased	7	1	8
	General physical condition abnormal	2	0	2
	Haematocrit decreased	1	0	1
	Haematocrit increased	1	0	1
	Haemoglobin decreased	1	0	1
	Heart rate increased	15	4	19
	Heparin-induced thrombocytopenia test positive	3	0	3

	Interleukin level increased	1	0	1
	Liver function test abnormal	1	0	1
	Oxygen saturation decreased	3	0	3
	Platelet count decreased	4	0	4
	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	3	0	3
Metabolism and nutrition disorders	Decreased appetite	52	4	56
	Gout	1	0	1
	Hypoglycaemia	1	0	1
	Hypovolaemia	1	0	1
	Lactic acidosis	2	0	2
Musculoskeletal and connective tissue disorders	Arthralgia	455	32	487
	Arthritis	4	0	4
	Back pain	23	5	28
	Bone pain	2	0	2
	Fibromyalgia	1	0	1
	Joint stiffness	0	1	1
	Limb discomfort	9	1	10
	Muscle spasms	11	0	11
	Muscle swelling	1	0	1
	Muscle twitching	1	0	1
	Muscular weakness	10	3	13
	Musculoskeletal stiffness	54	1	55
	Myalgia	905	68	973
	Myosclerosis	1	0	1
	Neck pain	14	1	15
	Osteoarthritis	1	0	1
	Pain in extremity	62	8	70
	Spinal deformity	0	1	1
	Spinal pain	0	1	1
Nervous system disorders	Ageusia	4	0	4
	Altered state of consciousness	2	1	3
	Amnesia	4	0	4
	Anosmia	2	0	2
	Aphasia	3	0	3
	Areflexia	1	0	1
	Balance disorder	5	1	6
	Bell's palsy	1	0	1
	Burning sensation	2	0	2
	Carotid artery thrombosis	1	0	1
	Cerebellar stroke	1	0	1
	Cerebral haemorrhage	4	0	4
	Cerebral infarction	2	0	2
	Cerebral thrombosis	2	0	2

	Cerebrovascular accident	5	0	5
	Depressed level of consciousness	4	0	4
	Disturbance in attention	7	1	8
	Dizziness	38	5	43
	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	1105	82	1 187
	Hemiparaesthesia	0	1	1
	Hemiparesis	2	0	2
	Hemiplegia	4	0	4
	Hyperaesthesia	4	0	4
	Hypoesthesia	6	5	11
	Ischaemic stroke	1	0	1
	Loss of consciousness	3	1	4
	Memory impairment	2	0	2
	Meningism	0	1	1
	Migraine	21	0	21
	Monoplegia	1	0	1
	Motor dysfunction	1	0	1
	Muscle contractions involuntary	1	0	1
	Nervous system disorder	31	7	38
	Neuralgia	1	0	1
	Neuropathy peripheral	1	0	1
	Pachymeningitis	1	0	1
	Paraesthesia	12	2	14
	Presyncope	1	1	2
	Restless legs syndrome	3	0	3
	Seizure	15	6	21
	Sensory loss	2	1	3
	Somnolence	8	2	10
	Speech disorder	2	0	2
	Spinal cord infarction	1	0	1
	Spinal cord ischaemia	1	0	1
	Syncope	13	4	17
	Taste disorder	2	1	3
	Transient ischaemic attack	3	0	3
	Tremor	16	3	19
	Unresponsive to stimuli	3	0	3
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	12	0	12
Daydreaming	1	0	1
Delusion	0	1	1
Depressed mood	0	1	1
Depression	1	0	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
Neurogenic bladder	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
Urinary retention	1	0	1
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	3	0	3
Choking sensation	1	0	1
Chronic obstructive pulmonary disease	1	0	1
Cough	18	0	18

Dysphonia	2	0	2
Dyspnoea	45	1	46
Dyspnoea exertional	4	0	4
Epistaxis	9	2	11
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	15	1	16
Pulmonary oedema	2	0	2
Pulmonary pain	1	0	1
Rales	1	0	1
Respiratory disorder	79	12	91
Respiratory distress	2	0	2
Rhinorrhoea	2	2	4
Sneezing	1	0	1
Stridor	1	0	1
Tachypnoea	1	0	1
Throat irritation	1	0	1
Wheezing	2	0	2
Skin and subcutaneous tissue disorders			
Angioedema	2	2	4
Blister	1	0	1
Cold sweat	2	1	3
Dermatitis allergic	1	0	1
Eczema	1	0	1
Erythema	8	0	8
Erythema multiforme	0	1	1
Hyperhidrosis	55	3	58
Miliaria	2	0	2
Night sweats	1	1	2
Pain of skin	8	0	8
Petechiae	5	3	8
Photosensitivity reaction	2	0	2
Pruritus	9	1	10
Psoriasis	1	0	1
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 discolouration	1	1	2
Skin disorder	51	17	68
Skin lesion inflammation	1	0	1
Skin mass	1	0	1

	Skin odour abnormal	1	0	1
	Urticaria	4	4	8
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
	Eye laser surgery	1	0	1
Vascular disorders	Arterial thrombosis	1	0	1
	Arteriosclerosis	0	1	1
	Bloody discharge	1	0	1
	Capillary leak syndrome	1	0	1
	Cyanosis	2	3	5
	Deep vein thrombosis	13	3	16
	Flushing	1	0	1
	Giant cell arteritis	1	0	1
	Haematoma	4	3	7
	Haemodynamic instability	1	0	1
	Haemorrhage	1	0	1
	Hot flush	8	0	8
	Hypertension	18	3	21
	Hypertensive crisis	1	0	1
	Hypotension	17	2	19
	Hypovolaemic shock	2	0	2
	Ischaemia	1	0	1
	Jugular vein thrombosis	1	0	1
	Pallor	1	0	1
	Pelvic venous thrombosis	0	1	1
	Peripheral coldness	3	1	4
	Peripheral ischaemia	1	0	1
	Peripheral vascular disorder	1	0	1
	Peripheral venous disease	1	1	2
	Periphlebitis	0	1	1
	Phlebitis	2	2	4
	Phlebitis superficial	0	1	1
	Subclavian artery thrombosis	1	0	1
	Thrombophlebitis	2	0	2
	Thrombophlebitis superficial	3	1	4
	Thrombosis	8	3	11
	Varicose vein	1	1	2
	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>9808</b>	<b>883</b>	<b>10 691</b>

