

### Summary Tabulation 06-04-2021

Active Substance (High Level)		VAXZEVRIA (COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19))		
Reaction SOC	Reaction PT	Serious	Non Serious	Total
Blood and lymphatic system disorders	Coagulopathy	8	7	15
	Coombs negative haemolytic anaemia	1	0	1
	Disseminated intravascular coagulation	1	0	1
	Lymphadenopathy	4	0	4
	Neutropenia	1	1	2
	Thrombocytopenia	3	3	6
Cardiac disorders	Angina pectoris	2	0	2
	Arrhythmia	1	0	1
	Bradycardia	1	1	2
	Cardiac failure	1	0	1
	Cardiovascular disorder	20	4	24
	Palpitations	19	2	21
	Tachycardia	20	3	23
Ear and labyrinth disorders	Deafness	0	1	1
	Deafness unilateral	2	0	2
	Ear discomfort	2	0	2
	Ear pain	7	0	7
	Hyperacusis	3	0	3
	Tinnitus	3	0	3
	Vertigo	13	0	13
Endocrine disorders	Adrenocortical insufficiency acute	1	0	1
	Goitre	1	0	1
Eye disorders	Amaurosis fugax	1	0	1
	Blindness	1	1	2
	Blindness unilateral	3	0	3
	Eye haemorrhage	0	1	1
	Eye irritation	1	0	1
	Eye pain	1	0	1
	Eye swelling	1	0	1
	Miosis	1	0	1
	Mydriasis	1	0	1
	Ocular discomfort	1	0	1
	Photophobia	5	0	5
	Retinal artery thrombosis	1	0	1
	Retinal ischaemia	1	0	1
	Vision blurred	3	0	3
	Visual impairment	5	0	5

Gastrointestinal disorders	Abdominal discomfort	2	0	2
	Abdominal distension	1	0	1
	Abdominal pain	10	1	11
	Abdominal pain upper	11	0	11
	Colitis ischaemic	1	0	1
	Colitis ulcerative	1	0	1
	Constipation	1	0	1
	Crohn's disease	1	0	1
	Diarrhoea	25	0	25
	Diarrhoea haemorrhagic	0	1	1
	Dry mouth	2	0	2
	Dyspepsia	1	0	1
	Eructation	1	0	1
	Flatulence	1	0	1
	Gastrointestinal disorder	1	0	1
	Gastrointestinal pain	1	0	1
	Gastrooesophageal reflux disease	1	0	1
	Glossodynia	1	0	1
	Intestinal congestion	1	0	1
	Intestinal infarction	1	0	1
	Intestinal ischaemia	1	0	1
	Lip pain	1	0	1
	Nausea	448	24	472
	Oesophageal spasm	1	0	1
	Oral discomfort	1	0	1
	Paraesthesia oral	2	0	2
	Rectal haemorrhage	0	1	1
	Regurgitation	1	0	1
	Retching	1	0	1
	Splanchnic hypoperfusion	1	0	1
	Thrombosis mesenteric vessel	1	0	1
Vomiting	41	1	42	
General disorders and administration site conditions	Application site joint warmth	1	0	1
	Asthenia	22	0	22
	Axillary pain	2	1	3
	Chest discomfort	0	1	1
	Chest pain	10	0	10
	Chills	815	44	859
	Death	1	0	1
	Extensive swelling of vaccinated limb	26	0	26
	Face oedema	2	0	2
	Facial pain	0	1	1
	Fatigue	772	39	811
	Feeling abnormal	4	1	5
	Feeling cold	21	1	22
	Feeling drunk	0	1	1
	Feeling hot	8	1	9
	Feeling of body temperature change	10	1	11
	General physical health deterioration	1	0	1
	Hyperthermia	2	1	3

	Hypothermia	2	0	2
	Induration	1	0	1
	Influenza like illness	79	5	84
	Injected limb mobility decreased	1	0	1
	Injection site discomfort	2	0	2
	Injection site erythema	13	0	13
	Injection site haematoma	1	0	1
	Injection site hypoaesthesia	1	0	1
	Injection site induration	5	0	5
	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	73	0	73
	Injection site paraesthesia	1	0	1
	Injection site rash	1	0	1
	Injection site reaction	403	26	429
	Injection site swelling	14	0	14
	Injection site warmth	9	0	9
	Local reaction	1	0	1
	Malaise	425	29	454
	No adverse event	1	0	1
	Oedema	1	0	1
	Pain	12	1	13
	Peripheral swelling	53	4	57
	Pyrexia	796	42	838
	Swelling	2	2	4
	Swelling face	1	0	1
	Thirst	1	0	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
	Portal vein occlusion	1	0	1
	Venoocclusive liver disease	1	0	1
Immune system disorders	Anaphylactic reaction	5	1	6
	Autoimmune disorder	2	0	2
	Hypersensitivity	25	6	31
Infections and infestations	COVID-19	7	0	7
	Conjunctivitis viral	0	1	1
	Cystitis	1	0	1
	Herpes zoster	0	1	1
	Influenza	6	0	6
	Lymphangitis	0	1	1
	Nasopharyngitis	1	0	1
	Sepsis	1	0	1

	Streptococcal infection	1	0	1
	Tooth abscess	1	0	1
	Urinary tract infection	1	0	1
Injury, poisoning and procedural complications	Contusion	0	1	1
	Fall	1	0	1
	Kidney rupture	1	0	1
	Maternal exposure during breast feeding	1	0	1
	Medication error	0	1	1
Investigations	Babinski reflex test	1	0	1
	Blood pressure decreased	5	0	5
	Blood pressure increased	1	0	1
	Body temperature decreased	1	0	1
	Body temperature increased	3	0	3
	Fibrin D dimer increased	1	0	1
	General physical condition abnormal	2	0	2
	Haematocrit decreased	1	0	1
	Heart rate increased	8	2	10
	Oxygen saturation decreased	2	0	2
	Platelet count decreased	1	0	1
	Red blood cell count decreased	1	0	1
	Respiratory rate decreased	0	1	1
Metabolism and nutrition disorders	Decreased appetite	36	2	38
	Lactic acidosis	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	309	17	326
	Arthritis	3	0	3
	Back pain	20	1	21
	Bone pain	1	0	1
	Fibromyalgia	1	0	1
	Limb discomfort	5	1	6
	Muscle spasms	8	0	8
	Muscle swelling	1	0	1
	Muscular weakness	4	0	4
	Musculoskeletal stiffness	43	1	44
	Myalgia	662	43	705
	Myosclerosis	1	0	1
	Neck pain	10	1	11
	Osteoarthritis	1	0	1
	Pain in extremity	41	3	44
	Spinal pain	0	1	1
Nervous system disorders	Ageusia	2	0	2
	Altered state of consciousness	2	1	3
	Amnesia	1	0	1
	Anosmia	1	0	1
	Aphasia	1	0	1
	Balance disorder	3	0	3
	Cerebral haemorrhage	1	0	1
	Cerebral thrombosis	6	0	6
	Cerebrovascular accident	3	0	3
	Depressed level of consciousness	1	0	1
	Disturbance in attention	2	1	3

	Dizziness	24	3	27
	Dysarthria	1	0	1
	Dysgeusia	3	1	4
	Facial paralysis	2	0	2
	Head discomfort	2	0	2
	Headache	796	51	847
	Hemiplegia	1	0	1
	Hyperaesthesia	4	0	4
	Hypoaesthesia	2	3	5
	Meningism	0	1	1
	Migraine	13	0	13
	Muscle contractions involuntary	1	0	1
	Nervous system disorder	11	3	14
	Neuralgia	1	0	1
	Paraesthesia	4	1	5
	Restless legs syndrome	1	0	1
	Seizure	14	6	20
	Somnolence	7	0	7
	Spinal cord ischaemia	1	0	1
	Syncope	10	1	11
	Taste disorder	2	0	2
	Tremor	13	0	13
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	1	0	1
Product issues	Oversensing	1	0	1
Psychiatric disorders	Agitation	2	0	2
	Anxiety	1	0	1
	Confusional state	4	0	4
	Delusion	0	1	1
	Depressed mood	0	1	1
	Eating disorder	1	0	1
	Hallucination	0	1	1
	Hallucination, visual	1	0	1
	Initial insomnia	1	0	1
	Insomnia	15	0	15
	Nightmare	1	0	1
	Phonophobia	1	0	1
	Restlessness	2	0	2
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	4	0	4
	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	Breast inflammation	1	0	1

	Breast pain	2	0	2
	Dysmenorrhoea	0	1	1
	Menorrhagia	1	0	1
	Menstrual disorder	0	1	1
	Vaginal haemorrhage	1	0	1
Respiratory, thoracic and mediastinal disorders	Asthma	2	0	2
	Chronic obstructive pulmonary disease	1	0	1
	Cough	16	0	16
	Dysphonia	1	0	1
	Dyspnoea	21	0	21
	Dyspnoea exertional	3	0	3
	Epistaxis	1	1	2
	Hyperventilation	4	0	4
	Nasal congestion	1	0	1
	Oropharyngeal pain	7	0	7
	Painful respiration	1	0	1
	Pharyngeal paraesthesia	0	1	1
	Pharyngeal swelling	1	0	1
	Pleural effusion	2	0	2
	Pulmonary embolism	1	0	1
	Pulmonary pain	1	0	1
	Respiratory disorder	60	9	69
	Respiratory distress	1	0	1
	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	Blister	1	0	1
	Dermatitis allergic	1	0	1
	Erythema	4	0	4
	Hyperhidrosis	39	2	41
	Night sweats	1	1	2
	Pain of skin	7	0	7
	Petechiae	1	0	1
	Photosensitivity reaction	2	0	2
	Pruritus	7	1	8
	Rash	3	1	4
	Rash erythematous	2	0	2
	Rash papular	0	1	1
	Rash pruritic	1	0	1
	Sensitive skin	2	0	2
	Skin disorder	30	6	36
	Skin lesion inflammation	1	0	1
	Skin odour abnormal	1	0	1
	Urticaria	2	1	3
Social circumstances	Impaired work ability	2	0	2
Surgical and medical procedures	Bed rest	1	0	1
	Explorative laparotomy	1	0	1
Vascular disorders	Arterial thrombosis	1	0	1

	Cyanosis	1	2	3
	Deep vein thrombosis	0	1	1
	Giant cell arteritis	1	0	1
	Haematoma	1	0	1
	Haemodynamic instability	1	0	1
	Hot flush	5	0	5
	Hypertension	4	1	5
	Hypotension	9	1	10
	Hypovolaemic shock	1	0	1
	Pallor	1	0	1
	Peripheral coldness	1	0	1
	Peripheral ischaemia	1	0	1
	Phlebitis	0	1	1
	Thrombosis	3	0	3
	Vascular rupture	1	0	1
	Venous thrombosis	1	0	1
	Venous thrombosis limb	0	1	1
<b>Total</b>		<b>6802</b>	<b>447</b>	<b>7 249</b>