

Worldwide Reference Number

MHRA ADR Number

MHRA Version Number

5

Company Reference No

Flag Key

Y - Yes

N - No

U - Unknown

Literature Reference

Duplicate ADR Numbers

Patient Details

Initials	Patient Sex	Patient Age	Patient Age Group	Patient Weight (kg)	Patient Last Menstrual Date	Gestation Period at Time of Reaction
PRIVACY	MALE	59YEARS	ADULT			

Report Seriousness

Reporter Considered Serious	Congenital Abnormality	Disability / Incapacity	Hospitalised Due to Reaction	Life Threatening	Patient Died	Other Medically Significant
Y	N	N	Y	Y	N	N

Parent/ Child (P/C) Reaction: Parent Details

Parent Sex	Parent Age	Parent Weight (kg)	Parent Last Menstrual Date

Drug/ Product Details

Product Name	Drug Characterisation	Active Constituent (S)
COVID-19 VACCINE ASTRAZENECA	SUSPECT	CHADOX1 NCOV-19

Drug Name	Drug Characterisation	Batch Number	Indication Name	Patient Route of Administration	Dose	Dosages/Interval
COVID-19 VACCINE ASTRAZENECA	SUSPECT	AB003				

Drug Name	Drug Characterisation	Strength	Drug Start Date	Drug End Date	Duration	Rechallenge Flag	Action Taken With Drug	Gestation Period at Time of Exposure
COVID-19 VACCINE ASTRAZENECA	SUSPECT		22/01/2021	22/01/2021		UNKNOWN	NOT APPLICABLE	

Reported Reaction Details

Reaction (LLT)	Meddra Version	PT Term	Reaction Outcome	Reaction Start Date	Reaction End Date	Onset Time (Start of Drug)	Reaction Duration	Recovery Time	Severity of Reaction	Reaction Treated?	Treatment Description
HEADACHE	23.1	HEADACHE	UNKNOWN			6DAY			UNKNOWN	Unknown	
INTRACEREBRAL BLEED	23.1	CEREBRAL HAEMORRHAGE	NOT RECOVERED/ NOT RESOLVED	03/02/2021		12DAY			UNKNOWN	Unknown	
INTRACRANIAL VENOUS SINUS THROMBOSIS	23.1	CEREBRAL VENOUS SINUS THROMBOSIS	NOT RECOVERED/ NOT RESOLVED	03/02/2021		12DAY			UNKNOWN	Unknown	
MUSCLE WEAKNESS LOWER LIMB	23.1	MUSCULAR WEAKNESS	UNKNOWN						UNKNOWN	Unknown	
SEIZURE	23.1	SEIZURE	UNKNOWN						UNKNOWN	Unknown	
SPEECH DISORDER	23.1	SPEECH DISORDER	UNKNOWN						UNKNOWN	Unknown	
THROMBOCYTOPENIA	23.1	THROMBOCYTOPENIA	UNKNOWN						UNKNOWN	Unknown	
UNILATERAL WEAKNESS OF LIMBS	23.1	HEMIPARESIS	UNKNOWN						UNKNOWN	Unknown	

Fatal Report

Patient Death Date	Post Mortem Performed Flag	COD Unknown Flag	Sudden Death Flag

Reported Cause(s) of Death

Patient History

Patient Med History Terms (LLT)	Patient Med Hist Continuing Flag	Patient Episode Start Date	Patient Episode End Date	Patient Med Hist Comments
THROMBOCYTOPENIA	Y			unknown aetiology ?malignancy but this has not yet been confirmed

Patient Drug History

Patient Historic Drug Name	Patient Hist Indication Term(s)	Drug Start Date	Drug End Date	Patient Hist Reaction Term(s)

Parent History

Parent Med History Terms (LLT)	Parent Med Hist Continuing Flag	Parent Medical Start Date	Parent Medical End Date	Parent Med Hist Comments

Parent Drug History

Parent Historic Drug Name	Parent Hist Indication Term(s)	Parent Past Drug Start Date	Parent Past Drug End Date	Parent Hist Reaction Term(s)



Test Results

Test Performed Date	Test Name	Test Result	Low Test Range	High Test Range	Report On File Flag
02/2021	BRAIN CT	ACUTE PARENCHYMAL BLEED			N
02/2021	BRAIN CT	THROMBOSIS POSTERIOR FRONTAL-PARIETAL CORTICAL VEI			N
02/2021	CT ANGIOGRAPHY	VENOUS SINUS THROMBOSIS			N
02/2021	GLASGOW COMA SCALE	DROPPED			N
	COVID-19 VIRUS TEST	NO - NEGATIVE COVID-19 TEST			N

Additional Test

Reaction Text:

Intracranial venous sinus thrombosis. Patient has not tested positive for COVID-19 since having the vaccine. Patient has not had symptoms associated with COVID-19. Patient is not enrolled in clinical trial. FU 05/02/2021: Patient developed generalised headache around 6 days after having the vaccine. Headache increased in severity over the course of 3 days. Developed bilateral leg weakness, then developed left sided upper and lower limb weakness. Subsequently developed speech difficulties. Was brought to hospital by ambulance. Whilst in triage he had a generalised seizure. Initially assessed by the stroke team for a presumed stroke. A CT scan of his brain was conducted which showed thrombosis of the posterior frontal-parietal cortical veins with an acute parenchymal bleed in the right posterior frontal lobe. The diagnosis of Venous Sinus Thrombosis was confirmed with a CT angiogram. The patient then dropped their Glasgow Coma Scale (GCS) and was intubated and admitted to intensive care unit (ICU). Nil other intercurrent event that may have contributed. No known risk factors for thrombosis. the patient was not taking antithrombotic medication. The patient was noted to have a thrombocytopenia of unknown aetiology ?malignancy but this has not yet been confirmed.

Reporter Comments: