

Worldwide Reference Number

MHRA ADR Number

MHRA Version Number

6

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	19YEARS				

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	Y

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	AB0003	COVID-19 VACCINATION			

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		27/01/2021	27/01/2021		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
CEREBRAL VENOUS SINUS THROMBOSIS	23.1	CEREBRAL VENOUS SINUS THROMBOSIS	UNKNOWN	02/2021					UNKNOWN	Unknown	
FEELING UNWELL	23.1	MALaise	UNKNOWN						UNKNOWN	Unknown	
IMMUNE THROMBOCYTOPENIA	23.1	IMMUNE THROMBOCYTOPENIA	UNKNOWN	02/2021					UNKNOWN	Unknown	
INTRACRANIAL HEMORRHAGE	23.1	HAEMORRHAGE INTRACRANIAL	RECOVERING/ RESOLVING	02/2021					UNKNOWN	Unknown	
PERSISTENT HEADACHE	23.1	HEADACHE	UNKNOWN	02/2021					UNKNOWN	Unknown	

Fatal Report

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

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
SURGERY	N			

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
	COVID-19 VIRUS TEST	NO - NEGATIVE COVID-19 TEST			N

Additional Test

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Reaction Text:

Patient fell unwell after getting the AstraZeneca jab from the university and since then had persistent headaches which finally culminated in him sustaining a cerebral venous sinus thrombosis, immune thrombocytopenia and intracranial bleeding. Follow up message: I am not the patient's doctor. It is the student's father who has told me of the reaction [REDACTED] I have emailed him, asking him to forward your email to the patient's consultant. He is currently in the intensive care unit (ICU) post-surgery. Patient has not had symptoms associated with COVID-19. Unsure if patient is enrolled in clinical trial. Requested follow up received 18/03/2021 Unfortunately, we have very little further information. We were informed by colleagues from the medical school where the individual is a student. We administered the vaccine as a vaccination centre but he is not a registered patient of ours so we have no further clinical information beyond the following narrative from the medical school - [REDACTED] who had the Covid -19 vaccine recently fell unwell after getting the AstraZeneca vaccine. He had persistent headaches which finally culminated in him sustaining a cerebral venous sinus thrombosis, immune thrombocytopenia and intracranial bleeding. He is currently in intensive care unit post-surgery. He received his vaccination as a front line healthcare worker (medical student) but is not a registered patient of the practice. For the local team I have conducted a desk top review of the assessment and vaccination process and can confirm that they are all in line with the standard operating procedures. The consent and vaccination details were recorded into the clinical system in real time and the patient received this first dose of AZ ChAdOx1 Batch number AB0003 at [REDACTED] on the 27th January 2021.

Reporter Comments:

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