Medicines & Healthcare products Regulatory Agency

Decision

Information for UK recipients on COVID 19 Vaccine AstraZeneca

Updated 15 April 2021

Contents Regulation 174 Information for UK recipients

Extremely rare cases of blood clots with low levels of platelets have been observed following vaccination with COVID-19 Vaccine AstraZeneca. The majority of these cases occurred within the first 14 days following vaccination but some have also been reported after this period. Some cases were life-threatening or had a fatal outcome. It is important to remember the benefits of vaccination to give protection against COVID-19 still outweigh any potential risks.

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-uk-recipients-on-covid-19-vaccine-astrazeneca

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 03-Jun-2021 Data Lock Date: 02-Jun-2021 18:30:03
Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Vena cava thrombosis	3	1
Vascular disorders SOC TOTAL	10045	54
TOTAL REACTIONS FOR DRUG	717250	863
TOTAL REPORTS	195641	
TOTAL FATAL OUTCOME REPORTS		863

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/992565/COVID-19_AstraZeneca_Vaccine_Analysis_Print_-_DLP_02.06.2021.pdf

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It is estimated that only 10% of serious reactions and between 2 and 4% of non-serious reactions are reported. Under-reporting coupled with a decline in reporting makes it especially important to report all suspicions of adverse drug reactions to the Yellow Card Scheme.

https://www.gov.uk/drug-safety-update/yellow-card-please-help-to-reverse-the-decline-in-reporting-of-suspected-adverse-drug-reactions