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Direct Healthcare Professional Communication

VAXZEVRIA/COVID-19 Vaccine AstraZeneca: contraindication in individuals with previous capillary leak syndrome

Dear Healthcare Professional,

Please also refer to previous Direct Healthcare Professional Communications (DHPCs), 24 March, 13 April and 02 June 2021.

AstraZeneca AB in agreement with the European Medicines Agency and the Malta Medicines Authority would like to inform you of the following:

Summary

- **Very rare cases of capillary leak syndrome (CLS) have been reported in the first days after vaccination with Vaxzevria. A history of CLS was apparent in some of the cases. A fatal outcome has been reported.**

- **Vaxzevria is now contraindicated in individuals who have previously experienced episodes of CLS.**

- **CLS is characterised by acute episodes of oedema mainly affecting the limbs, hypotension, haemoconcentration and hypoalbuminaemia. Patients with an acute episode of CLS following vaccination require prompt recognition and treatment. Intensive supportive therapy is usually warranted.**

The Vaxzevria Summary of Product Characteristics (SmPC) will be updated accordingly with this information.

Background on the safety concern

COVID-19 Vaccine AstraZeneca is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with Vaxzevria, with an estimated reporting rate of one case for more than 5 million doses. A history of CLS was noted in some of the cases.

CLS is a rare disorder characterised by dysfunctional inflammatory response, endothelial dysfunction, and extravasation of fluid from the vascular space to the interstitial space leading to shock, haemoconcentration, hypoalbuminaemia and potentially consequent organ failure. Patients may present with a rapid swelling of the arms and legs, sudden weight gain and feel faint due to low blood pressure.

Some cases of systemic CLS reported in the literature have been triggered by COVID-19 infection. CLS occurs rarely in the general population with fewer than 500 cases described worldwide in the literature (National Organisation for Rare Disorders), however, it is likely that estimates are lower than the true event rates.

The European Medicines Agency has recommended an update to the product information of the Vaxzevria suspension for injection to reflect the current knowledge of the safety topic.

Call for reporting

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are reminded to continue to report suspected adverse reactions associated with Vaxzevria in accordance with the national spontaneous reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Post-licensing directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta or sent by email to postlicensing.medicinesauthority@gov.mt.

Company contact point

Should you have any questions or require additional information, please contact AstraZeneca Medical Information at:

Company	Product Name	Website	Phone
Associated Drug Company Limited Triq l-Esportaturi, Zone 1, Central Business District, Birkirkara CBD 1040 Malta	Vaxzevria/COVID-19 Vaccine AstraZeneca	www.azcovid-19.com	+356 22778134

Yours faithfully,

Post-Licensing Directorate

Medicines Authority

Disclaimer

This Direct Healthcare Professional Communication has been submitted to you on behalf of AstraZeneca AB and their local representative Associated Drug Company Limited