

21<sup>st</sup> June 2021

## **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<sup>th</sup> March, 13<sup>th</sup> April and 2<sup>nd</sup> June, 2021.

AstraZeneca AB in agreement with the European Medicines Agency and the Health Products Regulatory Authority (HPRA) 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

Healthcare professionals should report any suspected adverse reactions associated with the use of Vaxzevria in accordance with the national spontaneous reporting system:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie) and include the batch/lot number if available.

Adverse events should also be reported to AstraZeneca Patient Safety on 1800 812456.

Please note the importance of reporting the vaccine product name and batch details.

## Company contact point


### AstraZeneca Medical Information

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Yours Faithfully

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