



Direct Healthcare Professional Communication

27-June-2021

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

Dear Healthcare Professional,

Please refer to previous Direct Healthcare Professional Communications (DUIPC) of 8 April, 2021 and 6 June, 2021

VACSERA in agreement with the Egyptian Pharmaceutical Vigilance Center in The Egyptian Drug 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 COVID-19 Vaccine AstraZeneca. A history of CLS was apparent in some of the cases. A fatal outcome has been reported.**
- **COVID-19 Vaccine AstraZeneca is now contraindicated in individuals who have previously experienced episodes of CLS.**
- **CLS is characterized 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 Covid-19 Vaccine AstraZeneca Summary of Product Characteristics (SmPC) has been updated accordingly with this information.

The Egyptian Drug Authority is following closely all safety updates outside Egypt and along with the ministry of health is evaluating all reported adverse events cases within Egypt to detect any change in the vaccine safety profile.

Background on the safety concern

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COVID-19 Vaccine AstraZeneca is indicated for active immunization 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 COVID-19 Vaccine AstraZeneca 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 is important. It allows continued monitoring of the benefit/risk balance of COVID-19 Vaccine AstraZeneca. Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: Egyptian Pharmaceutical Vigilance Center

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451 Telephone: +202- 25354100, Extension: 1470 Fax: +202 – 23610497

Email: pv.followup@edaegypt.gov.eg

Online reporting: <https://primaryreporting.who-umc.org/EG>

QR Code:



Company contact point:

Name: VACSERA (The Holding Company for Biological Products and Vaccines) **Address:** 51 Wezaret El-Zeraa-Agouza-Giza-Egypt **Telephone:** +202 37603922 +202 37611111, Extension: 7222,7134

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