DIR-25269-31924526

02 August 2021 №5683

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

Dear Healthcare Professional, JCS "R-Pharm" as an AstraZeneca authorized representative in territory of Saudi Arabia, acceding to request of the Saudi food and the Drug Authority (SFDA) 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.**
- **R-Covi 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 R-Covi Summary of Product Characteristics (SPC) 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 R-Covi, 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

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.

Call for reporting

Healthcare professionals should report any suspected adverse reactions associated with the use of R-Covi in accordance with the national spontaneous reporting system.

If the adverse reactions events in Kingdom of Saudi Arabia, please report to:

Name: Abdulmohsen Almohaideb
Address: Riyadh - Alamalz
Tel: 00966545172455
Mob: 00966545172455
E-mail: PV@sitcopharma.com

SFDA contacts:
Pharmacovigilance Executive Directorate
Address: K.S.A. Riyadh – Hitteen Dist Northern Ring Branch Road
Tel: 00966112038222
E-mail: NPC.Drug@sfda.gov.sa

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

This document is reviewed and approved by The Executive Directorate of Pharmacovigilance, at SFDA.

R_Pharm group Company contact point
Leninskij prospekt 111/1, 119421 Moscow, Russia
tel.: +7 (495) 956-79-37 (3829)
mob.: +7 (926) 620-55-83
E-mail: safety@rpharm.ru

Yours Faithfully
Head of Drug Safety and Pharmacovigilance
of R-Pharm Group, QPPV
Aleksey Skripkin

A. Skripkin
02 Aug 2021