SFDA
Safety Communication

3 August 2021

The Saudi Food and Drug Authority Statement on Reports of Capillary Leak Syndrome Following AstraZeneca COVID-19 Vaccine

The Saudi Food & Drug Authority (SFDA) would like to notify healthcare professionals about the potential risk of Capillary Leak Syndrome (CLS) following the use of AstraZeneca COVID-19 vaccine.

CLS is a rare disorder characterized by dysfunctional inflammatory response, endothelial dysfunction, and extravasation of fluid from the vascular space to the interstitial space leading to shock, haemoconcentration, hypoalbuminemia 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 CLS as reported in the literature have been triggered by COVID-19 infection. However, very rare reported cases CLS worldwide have been occurred in the first few days after vaccination with the AstraZeneca COVID-19 vaccine. A previous diagnosis of CLS was confirmed in some of the cases, and a fatal outcome has been reported.

The SFDA reviewed all the measures that have been established by the international regulatory bodies on the potential risk of CLS with AstraZeneca COVID-19 vaccine. Therefore, the SFDA considered the relationship between AstraZeneca COVID-19 vaccine and CLS as possible.

Overall, the potential benefits of AstraZeneca COVID-19 vaccine continue to outweigh any potential risks, and based on that, the SFDA recommends the following:

1- CLS is a serious, potentially fatal condition occurred very rarely and within days following vaccination with AstraZeneca COVID-19 vaccine.

2- Healthcare Providers should advise people receiving AstraZeneca COVID-19 vaccine to seek immediate medical attention if they develop symptoms suggestive of CLS such as swelling of the arms and legs, sudden weight gain and feeling faint within days following vaccination.
3- AstraZeneca COVID-19 vaccine is contraindicated in individuals who have previously experienced episodes of CLS.
4- The product information of AstraZeneca COVID-19 vaccine will be updated to include the risk of CLS.

The SFDA is carefully monitoring all the safety data of registered COVID-19 vaccines, including AstraZeneca COVID-19 vaccine, and will update any advice as necessary.

Call for reporting:

Healthcare professionals should report any suspected adverse events related to the use of COVID-19 vaccines to the National Pharmacovigilance Center via below reporting channels:

SFDA Call Center: 19999

COVID Vaccine adverse event electronic reporting form:

(https://ade.sfda.gov.sa/Covid/CovidRequest)

Email: NPC.drug@sfda.gov.sa