Date: 2021

Direct Healthcare Professional Communication

COVID-19 Vaccine AstraZeneca: Risk of thrombocytopenia and coagulation disorders

Dear Healthcare Professional,

VACSERA in agreement with the Ministry of Health and Population and Egyptian Drug Authority would like to inform you of the following:

Summary

- COVID-19 Vaccine AstraZeneca: benefits outweigh the risks despite possible link to very rare blood clots with low blood platelets.
- A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with COVID-19 Vaccine AstraZeneca.
- Healthcare professionals should be alert to the signs and symptoms of thromboembolism and or thrombocytopenia.
- Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling, and persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches and blurred vision after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.

Background on the safety concern

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.

Cases of thromboembolic events have been reported following administration of COVID-19 Vaccine AstraZeneca in several EEA countries, some leading to local suspensions of specific batches or to the use of the vaccine itself.

A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with COVID-19 Vaccine AstraZeneca. This includes severe cases presenting as venous thrombosis,

including unusual sites such as cerebral venous sinus thrombosis, mesenteric vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of these cases occurred within the first seven to fourteen days following vaccination and occurred in women

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under 55 years of age, however this may reflect the increased use of the vaccine in this population. Some cases had a fatal outcome.

Based on these events, the PRAC has initiated signal procedure in order to further investigate the issue.

The PRAC has performed a full investigation under accelerated timetable including a careful review of EudraVigilance case reports of blood clots and thrombocytopenia in individuals who received the vaccine paying special attention to the information on the sex, age, risk factors, COVID-19 diagnosis (if available), time-to-onset, outcome, and clinical entity.

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: (+2)02 25354100, Extension: 1311
Fax: +202 – 23610497
Email: pv.followup@edaegypt.gov.eg
Online reporting: http://www.edaegypt.gov.eg
QR code:

Company contact point:

Name: VACSERA (The Holding Company for Biological Products and Vaccines)
Address: 51 Wezaret El-Zeraa-Agouza-Giza-Egypt
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