



## Direct Healthcare Professional Communication

April-2021

### COVID-19 Vaccine AstraZeneca: Risk of coagulation disorders with or without thrombocytopenia

Dear Healthcare Professional,

VACSERA in agreement with the Egyptian Pharmaceutical Vigilance Center in The Egyptian Drug Authority would like to inform you of the following:

#### Summary

- The Benefits of COVID-19 Vaccine AstraZeneca **still** outweigh the **risks despite possible link to very rare cases of thrombosis and thrombocytopenia**, in some cases **accompanied by bleeding reported outside** Egypt.
- **Healthcare** providers **should** be alert to warning signs of thromboembolism and thrombocytopenia.
- Vaccinated individuals should be instructed to seek immediate medical help if they develop any of the following symptoms such as severe, persistent **headache and blurred vision, shortness of breath, chest pain**, leg swelling, severe **abdominal pain petechia** beyond the site of **vaccination** with onset between 4 to 20 days after vaccination

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

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 thrombosis and thrombocytopenia, sometimes 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 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 the currently available evidence, specific risk factors have not been confirmed.



### Recommendations to Healthcare Professionals:

- Healthcare providers should be alert to warning signs of thromboembolism and thrombocytopenia with an onset between 4 to 20 days after vaccination with COVID-19 Vaccine AstraZeneca. For CVST 'red flag' features include new onset *or* severe persistent headache that is not settling with analgesia. Patients may also present with features of raised intracranial pressure (acute severe headache, vomiting, confusion), focal neurological deficits and/or seizures.
- If a severe thrombotic complication with thrombocytopenia is suspected, refer the patient to an emergency department for further assessment and hematology consultation.
- Clinical investigations should include a full blood count (to look for thrombocytopenia), a D-dimer test, fibrinogen and radiological imaging as clinically indicated (for example brain CT or MRI for CVST).  
If screening tests suggest HIT-like thrombosis (low platelets  $<100 \times 10^9/L$  together with elevated D-dimer 2 x upper limit of normal [ULN] or reduced fibrinogen), a hematologist or hemostasis-thrombosis specialist should be consulted to advise on further investigations (including a HIT screen).
- Patients suspected to have this condition should NOT receive any heparin or platelet transfusions. These treatments may potentially worsen the clinical course.
- Patient should be instructed to seek medical attention if they presented any of the symptoms below.

### Patients should seek medical assistance immediately if they have any of the following symptoms:

- shortness of breath
- chest pain
- swelling in your leg
- persistent abdominal (belly) pain
- neurological symptoms. including severe and persistent headaches or blurred vision
- tiny blood spots under the skin beyond the site of injection

### Call for reporting



Code No. FM-PVC-03

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://www.edaegypt.gov.eg/>

QR Code:



#### Company contact point:

Name: VACSERA (The Holding Company for Biological Products an Vaccines)

Address: 51 Wezaret El-Zeraa-Agouza-Giza-Egypt

Telephone: +202 37603922

+202 37611111, Extension: 7222,7134

Email: [egyvac.pharmacovigilance@vacsera.com](mailto:egyvac.pharmacovigilance@vacsera.com)

#### Annexes

- Covid-19 vaccine AstraZeneca: benefits still outweigh the risks despite possible link to rare blood clots with low blood platelets. (<http://www.ema.europa.eu/en/new's/covid-19-vaccine-astrazeneca-benefits-still-outweigh-risks-despite-possible-link-rare-blood-clots>)
- <https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-ver'-rare-cases-unusual-blood-clots-low-blood>
- <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-recommended-use-astrazeneca-covid-19-vaccine-younger-adults.html>



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- Updated ATAGI statement for healthcare providers on a specific clotting condition being reported after COVID-19 vaccination. (<https://www.health.gov.au/news/atagi-statement-healthcare-providers-specific-clotting-condition-reported-after-covid-19-vaccination>)