



## Direct Healthcare Professional Communication

June-2021

### COVID-19 Vaccine AstraZeneca: Risk of thrombosis in combination with thrombocytopenia — Updated information

Dear Healthcare Professional,

Please refer to previous Direct Healthcare Professional Communication (DHPC) of April, 2021.

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

#### Summary

- Covid-19 Vaccine AstraZeneca is contraindicated in individuals who have experienced Thrombosis with Thrombocytopenia Syndrome (TTS) following previous vaccination with Covid-19 Vaccine AstraZeneca.
- TTS requires specialized clinical management. Healthcare professionals should consult applicable guidance and/or consult specialists (e.g., hematologists, specialists in coagulation) to diagnose and treat this condition.
- Individuals diagnosed with thrombocytopenia within 3 weeks after vaccination with Covid-19 Vaccine AstraZeneca should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia.

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

The 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.

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



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severe cases presenting as venous thrombosis. including in unusual sites, such as cerebral venous sinus thrombosis and splanchnic vein thrombosis. as well as arterial thrombosis, concomitant with thrombocytopenia. Some cases had a fatal outcome. The majority of these cases occurred in the first three weeks following vaccination and occurred mostly in women under 60 years of age.

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, leg pain, persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches, blurred vision, confusion or seizures after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.

Individuals presenting with thrombocytopenia within 3 weeks after vaccination should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia.

#### Information for healthcare professionals:

- The European Medicine Agency (EMA) is introducing a contraindication for COVID-19 Vaccine AstraZeneca in people who have had thrombosis with thrombocytopenia syndrome (TTS) after previously receiving this vaccine.
- As TTS requires specialist treatment, healthcare professionals should consult applicable guidance and/or specialists (e.g. a hematologist and coagulation specialist) to diagnose and treat the condition.
- Healthcare professionals should check for signs of thrombosis in any person who has thrombocytopenia within 3 weeks of vaccination with COVID-19 Vaccine AstraZeneca. Similarly. they should check for signs of thrombocytopenia in any person who has thrombosis within 3 weeks of vaccination.
- Healthcare professionals should continue to advise people to seek urgent medical attention if they have any symptoms suggestive of thrombosis or thrombocytopenia.

#### 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

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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 and 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

- Direct Health Care Professional Communication (DHPC): Vaxzevria/COVID-19 Vaccine AstraZeneca: Risk of thrombosis in combination with thrombocytopenia — Updated information. [https://www.ema.europa.eu/en/documents/dhpc/direct-healthcare-professional-communication-dhpc-xaxzevria/covid-19-vaccine-astrazeneca-risk-thrombosis-combination-thrombocytopenia-updated-information\\_en.pdf](https://www.ema.europa.eu/en/documents/dhpc/direct-healthcare-professional-communication-dhpc-xaxzevria/covid-19-vaccine-astrazeneca-risk-thrombosis-combination-thrombocytopenia-updated-information_en.pdf)
- Vaxzevria: further advice on blood clots and low blood platelets (<https://www.ema.europa.eu/en/news/vaxzevria-further-advice-blood-clots-low-blood-platelets>)
- 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/news/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-verv-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/ataei-statement-healthcare-providers-specific-clotting-condition-reported-after-covid-19-vaccination>)