

#### **Press release**

# Vaxzevria COVID-19 Vaccine: Further advice on blood clots and low blood platelets

EMA has provided additional advice on blood clots or low blood platelets occurring after vaccination with Vaxzevria (formerly COVID-19 Vaccine AstraZeneca).

EMA's human medicines committee (CHMP) is recommending that healthcare professionals:

- must not give Vaxzevria to anyone who has had blood clots with low blood platelets (thrombosis with thrombocytopenia syndrome, TTS) after receiving the vaccine.
- should check for signs of blood clots in any person who has low blood platelets within 3 weeks of vaccination.
- should check for signs of low blood platelets in any person who has blood clots within 3 weeks of vaccination.
- should ensure that patients who have blood clots with low blood platelets after vaccination receive specialist care.

While blood clots with low blood platelets following vaccination are <u>very rare</u>, EMA continues to advise people to be aware of symptoms (see below), so they can receive prompt specialised medical treatment if needed.

The updated EMA recommendations for healthcare professionals are available in the vaccine's product information. As for all vaccines, EMA and national authorities continuously monitor the safety of Vaxzevria and will update recommendations when necessary, to protect public health.

# REPUBLIC OF CYPRUS MINISTRY OF HEALTH

## Information for the public

- Cases of unusual blood clots with low platelets have occurred in people who received Vaxzevria (formerly COVID-19 Vaccine AstraZeneca).
- You must not have Vaxzevria if you have had blood clots with low platelets after receiving the vaccine.
- Your doctor will carry out tests if you have any type of blood clot or low blood platelets following vaccination.
- You must seek urgent medical attention immediately if you have any of the following symptoms within 3 weeks of your injection:
  - shortness of breath
  - chest pain
  - leg swelling
  - leg pain
  - persistent abdominal (belly) pain
  - neurological symptoms, such as severe and persistent headaches, blurred vision, confusion or seizures (fits)
  - unusual skin bruising or pinpoint round spots beyond the site of the injection.

# Information for healthcare professionals

- EMA is introducing a contraindication for Vaxzevria (formerly 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 haematologist 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 Vaxzevria. 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.

Healthcare professionals will receive a direct healthcare professional communication (DHPC) with the information above. The DHPC will also be available on a <u>dedicated page</u> on the EMA website.

### More about the medicine

Vaxzevria (formerly COVID-19 Vaccine AstraZeneca) is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 18 years and older. COVID-19 is caused by SARS-CoV-2 virus. Vaxzevria is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making the S protein from SARS-CoV-2. The vaccine does not contain the virus itself and cannot cause COVID-19.

The most common side effects are usually mild or moderate and improve within a few days after vaccination.

### More about the procedure

EMA's safety committee (PRAC) and human medicines committee (CHMP) conducted this review of Vaxzevria in the context of a procedure known as a 'type II variation'. The European Commission will issue a legally binding decision valid throughout the EU.

More information on EMA reviews concerning blood clots and low blood platelets with Vaxzevria, including the latest safety updates, is available on EMA's <u>website</u>.

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