Vaxzevria: further advice on blood clots and low blood platelets

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Information on Vaxzevria (formerly COVID-19 Vaccine AstraZeneca)

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

The following product is authorised via centralised procedure.

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
ChAdOx1-S	Vaxzevria (previously COVID-19 Vaccine AstraZeneca)	Suspension for injection	POM	EU/1/21/1529/001-002	AstraZeneca AB

Information from the EMA about the safety concern

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'. A European Commission decision on this opinion will be issued in due course.

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 very rare, 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 will be 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.

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

In Malta

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 dedicated page on the EMA website.

Advice for Patients

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.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Vaxzevria (formerly COVID-19 Vaccine AstraZeneca) medicinal products. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to: Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 **or** online to http://www.medicinesauthority.gov.mt/adrportal or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate

Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health.

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this form (address side up), stapling the ends and then posting (no stamp required).

Feedback:

We thank you for your interest and look forward to hearing your opinion.

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Pharmacovigilance Section

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Sir Temi Żammit Buildings

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