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AstraZeneca's COVID-19 vaccine: EMA to provide further context on risk of very rare blood clots with low blood platelets

EMA continues to monitor very rare blood clots with low blood platelets that occurred after vaccination with Vaxzevria (formerly COVID-19 Vaccine AstraZeneca).

In line with a request from the EU's Commissioner for Health and Food Safety following a meeting of EU Health Ministers, EMA is undertaking a review of vaccination data and data on disease epidemiology (including infection rates, hospitalisations, morbidity and mortality).

The review by EMA's human medicines committee (CHMP) will enable authorities to put the risks of Vaxzevria into the context of the benefits of ongoing vaccination campaigns. The Committee will also consider whether to update recommendations for a second dose of Vaxzevria in those who have already received the first dose.

EMA considers the overall benefits of the vaccine continue to outweigh the risks in people being vaccinated. The CHMP's review will support ongoing national vaccination campaigns in their decisions on how to optimally deploy the vaccine

As for all vaccines, EMA will continue to monitor Vaxzevria's safety and effectiveness and provide the public with the latest information.

More about the vaccine

Vaxzevria 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 a protein from SARS-CoV-2. The vaccine does not contain the virus itself and cannot cause COVID-19.

The most common side effects with Vaxzevria are usually mild or moderate and improve within a few days after vaccination. More information about the vaccine is available on EMA's website.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

More about the procedure

The European Commission requested this review under Article 5(3) of Regulation 726/2004 following an informal meeting of EU health ministers on 7 April 2021. The review will be carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), which is responsible for questions concerning medicines for human use. The CHMP's review will build on the work of EMA's safety committee (PRAC).