EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 May 2021

COVID-19 vaccine safety update

VAXZEVRIA

AstraZeneca AB

Individuals who previously had blood clots with low blood platelets (thrombosis with thrombocytopenia syndrome, TTS) after Vaxzevria must not be given a second dose of Vaxzevria.

Individuals with low blood platelets within 3 weeks after vaccination with Vaxzevria should be actively investigated for signs of blood clots; similarly, individuals who present with blood clots within 3 weeks of vaccination should be evaluated for low blood platelets.

Patients who have blood clots with low blood platelets after vaccination require specialist medical care.

Hypersensitivity reactions presenting as hives or rapid swelling under the skin in areas such as the face, lips, mouth and throat are newly identified side effects of Vaxzevria.

Vaxzevria is effective in preventing COVID-19.

This safety update follows the last update of 11 May 2021.

Safety updates provide information about the assessments of emerging worldwide safety data since marketing authorisation for COVID-19 vaccines. Safety assessments are carried out primarily by EMA's Pharmacovigilance Risk Assessment Committee (PRAC). The safety updates are published regularly at COVID-19 vaccines: authorised.

All published safety updates for Vaxzevria are available at Vaxzevria: safety updates.

Since its marketing authorisation in the European Union (EU) on 29 January 2021 until 20 May 2021, more than 37 million doses of Vaxzevria have been administered in the EU/EEA[1].

1. Updates on safety of Vaxzevria

At its meeting held on 20 May 2021, based on new safety data, PRAC assessed the following:

Embolic and thrombotic events with a focus on thrombosis with thrombocytopenia

Further to the PRAC assessment earlier in May 2021[2], PRAC and the Committee for Medicinal Products for Human Use (CHMP) finalised the updates to the product information of Vaxzevria with regard to thrombosis with thrombocytopenia syndrome (TTS, formation of blood clots in the vessels with low blood platelets), a very rare side effect. These updates include:

- a contraindication to not vaccinate individuals with Vaxzevria who have experienced TTS following vaccination with Vaxzevria;

- advice that individuals diagnosed with thrombocytopenia within 3 weeks after vaccination with Vaxzevria should be actively investigated for signs of thrombosis; similarly, individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia; and

- emphasis that TTS requires specialised clinical management; healthcare professionals should consult applicable guidance and/or consult specialists (e.g. haematologists, specialists in coagulation) to diagnose and treat this condition.

[1] The European Centre for Disease Prevention and Control (ECDC) collects these data from EU Member States as well as from the additional countries of the European Economic Area (EEA) Norway, Iceland and Liechtenstein.
[2] See Safety Update for Vaxzevria of 11 May 2021

A further direct healthcare professional communication (DHPC) will be sent out to raise awareness among healthcare professionals. The DHPC will be available on a dedicated page on the EMA website[3].

Hypersensitivity reactions - urticaria and angioedema

PRAC concluded an assessment of hypersensitivity (allergic) reactions with an update to the product information of Vaxzevria.

This will now include the hypersensitivity reaction of urticaria (hives [raised, red and itchy skin rash]) as a new uncommon side effect (i.e. occurring in less than 1 in 100 persons), as well as angioedema (rapid swelling under the skin in areas such as the face, lips, mouth and throat, which may cause difficulty in swallowing or breathing). For angioedema the available data did not allow an estimate of the frequency.

Hypersensitivity, rash, pruritus (itchy skin) and anaphylaxis (severe allergic reaction) are already included in the product information.

Acute macular neuroretinopathy (AMN)

PRAC is reviewing adverse event reports of acute macular neuroretinopathy (AMN), a rare condition characterised by sudden onset of one or more paracentral scotomas, i.e. spots that partially obstruct vision. This condition has been reported very rarely after vaccination with Vaxzevria. PRAC has requested further data and analyses from the marketing authorisation holder to continue the PRAC assessment of whether AMN could possibly be caused by Vaxzevria.

2. Other information for Vaxzevria

Vaxzevria (previously COVID-19 Vaccine AstraZeneca) is a vaccine that was authorised in the EU on 29 January 2021 for use in people aged 18 years and older to prevent COVID-19 when infected with the coronavirus SARS-CoV-2. COVID-19 is a potentially severe disease that may result in death.

Vaxzevria contains an adenovirus that has been modified to carry molecules of DNA, which the body uses to temporarily produce the SARS-CoV-2 spike protein. The spike protein does not cause COVID-19. The adenovirus cannot reproduce and does not cause viral disease.

Before Vaxzevria was granted an EU marketing authorisation, the efficacy and safety of the vaccine were assessed through pre-clinical studies and large clinical trials. More than 12,000 participants have been given the vaccine in clinical trials.

[3] See EMA Public Health Communication of 21 May 2021

Like all medicines, this vaccine can cause side effects, although not everybody will experience them. The most common side effects known for Vaxzevria are usually mild or moderate and get better within a few days after vaccination.

More information on how Vaxzevria works and its use is available in the medicine overview. This includes information on use in pregnant and breastfeeding women and immunocompromised individuals.

Information in all EU/EEA languages is available in the product information, which includes the summary of product characteristics and the package leaflet.

3. How safety is monitored

As for all COVID-19 vaccines, relevant new information emerging on Vaxzevria is collected and promptly reviewed. This is in line with the pharmacovigilance plan for COVID-19 vaccines of the EU regulatory network (comprising the regulatory bodies of the EU Member States, EMA and the European Commission).

Collecting case reports of suspected side effects

The EU regulatory network continuously monitors reports of suspected side effects observed in vaccinated individuals. These case reports are collected and recorded in EudraVigilance, a system operated by EMA for managing and analysing information on suspected side effects of medicines.

Vaccinated individuals and healthcare professionals should report suspected side effects via the national reporting systems, which also contribute to EudraVigilance. For more information, see Reporting suspected side effects. Information on how to report in your Member State is available in the package leaflet and via the list of national competent authorities.

You may visit EudraVigilance – European database of suspected drug reaction reports and search for "COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)" to see all suspected side effects reported for Vaxzevria in the EU/EEA. Please note that these reports describe suspected side effects in individuals, i.e. these events may not necessarily have been caused by, or be otherwise related to, the vaccine.

Planned and ongoing studies

The company that markets Vaxzevria will continue to provide results from the main clinical trials, which are ongoing. It will also conduct additional studies to monitor the safety and effectiveness of the vaccine as it is used in vaccination campaigns and other clinical practice. For the list of planned and ongoing safety studies for Vaxzevria, see the risk management plan.

A paediatric investigation plan (PIP) for Vaxzevria is in place. This describes how the company will collect data on the vaccine's efficacy and safety for its potential use in children.

In addition, EMA is coordinating observational studies in EU Member States looking at real-world data from clinical practice to monitor the safety and effectiveness of COVID-19 vaccines, including in pregnant women.

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