



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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# COVID-19 vaccine safety update

## VAXZEVRIA

AstraZeneca AB

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.

Vaxzevria is effective in preventing COVID-19.

This safety update follows the last update of 14 April 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 the European Union (EU) on 29 January 2021 until 6 May 2021, almost 30 million doses of Vaxzevria have been administered in the EU/EEA<sup>1</sup>.

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## 1. Updates on safety of Vaxzevria

At its meeting held 3 to 6 May 2021, based on new safety data including the latest Monthly Summary Safety Report (MSSR)<sup>2</sup> from the marketing authorisation holder, PRAC assessed the following:

### Emboic and thrombotic events with a focus on thrombosis with thrombocytopenia

Further to the PRAC assessment in April 2021<sup>3</sup> and an assessment by the [Committee for Medicinal Products for Human Use](#) (CHMP) of the vaccine's benefits and the risk of thrombosis with thrombocytopenia syndrome (TTS, formation of blood clots in the vessels with low blood platelets)<sup>4</sup>, PRAC considered the available evidence, including recent data from the marketing authorisation holder, for an ongoing procedure to further amend the product information regarding:

- a contraindication to not vaccinate individuals with Vaxzevria who have experienced TTS following vaccination with Vaxzevria before;
- advice that individuals diagnosed with thrombocytopenia within 3 weeks of vaccination with Vaxzevria should be actively investigated for signs of thrombosis, and similarly individuals who present with thrombosis following vaccination should be evaluated for thrombocytopenia;
- addition of leg pain, seizures (fits) and mental status change as possible signs and symptoms of TTS (in addition to the signs and symptoms already included in the product information: severe or persistent headache, blurred vision, skin bruising beyond the site of vaccination after a few days, shortness of breath, chest pain, leg swelling, or persistent abdominal pain);

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<sup>1</sup> 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.

<sup>2</sup> Monthly Summary Safety Reports, also referred to as pandemic summary safety reports, will be compiled by the marketing authorisation holders to support timely and continuous benefit-risk evaluations for COVID-19 vaccines used during the pandemic. These reports complement the submission of [Periodic Safety Update Reports](#) (PSURs).

<sup>3</sup> See [Safety Update for Vaxzevria of 14 April 2021](#)

<sup>4</sup> See [EMA Public Health Communication of 23 April 2021](#)

- advice that healthcare professionals should consult applicable guidance and/or consult specialists (e.g. haematologists, specialists in coagulation) to diagnose and treat TTS as this condition requires specialised clinical management; and
- information in the section on side effects to indicate that in clinical trials with Vaxzevria, transient mild thrombocytopenia was commonly reported (occurring in less than 1 in 10 persons).

Updates to the risk management plan (RMP) regarding TTS and thrombosis are currently under assessment.

PRAC has requested further data from the marketing authorisation holder to keep this safety issue under close monitoring.

## Immune thrombocytopenia (ITP)

PRAC assessed cases of immune thrombocytopenia (ITP, an auto-immune condition of low blood platelet levels that can lead to bruising and bleeding) reported with Vaxzevria. PRAC has requested further data from the marketing authorisation holder to continue its assessment.

## Guillain-Barré syndrome (GBS)

PRAC is assessing cases of Guillain-Barré syndrome (GBS) reported after vaccination with Vaxzevria in the context of its regular reviews of the MSSRs. GBS is an immune system disorder that causes nerve inflammation and can result in pain, numbness, muscle weakness and difficulty in walking. PRAC has requested the marketing authorisation holder to provide further detailed data, including an analysis of all the reported cases, in the context of the next MSSR<sup>5</sup>.

## 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

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<sup>5</sup> See [Meeting Highlights from the Pharmacovigilance Risk Assessment Committee \(PRAC\) 3-6 May 2021](#)

large clinical trials. More than 12,000 participants have been given the vaccine in clinical trials.

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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