



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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# COVID-19 vaccine safety update

VAXZEVRIA

AstraZeneca AB

The safety of Vaxzevria is continuously monitored and safety updates are regularly provided to the public. This document outlines the outcomes from the assessment of emerging worldwide safety data carried out by EMA's [Pharmacovigilance Risk Assessment Committee](#) (PRAC) (see section 1). It also contains high-level information from the reporting of suspected adverse reactions, which PRAC takes into account in its assessments (see section 2).

This safety update follows the update of 18 June 2021.

## Main outcomes from PRAC's latest safety assessment

Vaccinated persons need to seek immediate medical attention if they develop weakness and paralysis in the extremities, possibly progressing to the chest and face, after vaccination with Vaxzevria, as these could be signs of Guillain-Barré syndrome.

The product information will be updated.

Vaxzevria is effective in preventing COVID-19.

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 4 July 2021, more than 58.4 million doses of Vaxzevria have been administered in the EU/EEA<sup>1</sup>.



## 1. Updates on safety assessments for Vaxzevria

Based on new safety data, including the latest Monthly Summary Safety Report (MSSR)<sup>2</sup> from the marketing authorisation holder and data reported by patients and healthcare professionals to EudraVigilance (see section 2), PRAC assessed the following at its meeting held 5 to 8 July 2021:

### Guillain-Barré syndrome (GBS)

PRAC assessed cases of Guillain-Barré syndrome (GBS) reported after vaccination with Vaxzevria. GBS is an adverse event of special interest for all COVID-19 vaccines requiring specific safety monitoring.

GBS is an immune system disorder that causes nerve inflammation and can result in pain, numbness, muscle weakness and difficulty walking.

PRAC assessed all available evidence, including cases reported to EudraVigilance (see section 2) and information from the scientific literature. A total of 227 cases of GBS had been reported from the EU/EEA to EudraVigilance with Vaxzevria by 27 June 2021, while around 51.4 million doses of Vaxzevria had been given to people in the EU/EEA by 20 June 2021. Reported cases concern suspected side effects, i.e. medical events that have been observed after vaccination, but which are not

<sup>1</sup> The [European Centre for Disease Prevention and Control \(ECDC\)](#) collects these exposure 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).

necessarily related to or caused by the vaccine. At this stage the available data neither confirm nor rule out a causal relationship with the vaccine.

In view of the seriousness of this rare condition, however, PRAC recommended adding a statement to the sections for warnings and precautions of use in the product information to alert healthcare professionals and people taking the vaccine of this potential risk.

Healthcare professionals should be alert to signs and symptom of GBS, allowing early diagnosis, supportive care and treatment.

People taking the vaccine are advised to seek immediate medical attention if they develop weakness and paralysis in the extremities that can progress to the chest and face.

PRAC continues to closely monitor this issue<sup>3</sup>.

## Immune thrombocytopenia (ITP)

PRAC continued assessing 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.

## Acute macular neuroretinopathy (AMN)

PRAC assessed cases 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. For this assessment, ophthalmological diagnosis and causality are considered in each case. PRAC has requested further data and analyses from the marketing authorisation holder to continue its assessment of whether AMN could possibly be caused by Vaxzevria.

## Myocarditis and pericarditis

PRAC continued its assessment of myocarditis and pericarditis (inflammatory conditions of the heart) reported in a small number of people following vaccination with COVID-19 vaccines. As of end of May 2021, 38 cases of myocarditis and 47 cases of pericarditis were reported from the EU/EEA to EudraVigilance (see section 2) following vaccination with Vaxzevria; 40 million doses of the vaccine had been administered in the EU/EEA. Further information is needed to assess whether there is a causal relationship between myocarditis/pericarditis and Vaxzevria, and

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<sup>3</sup> See [PRAC Highlights of July 2021](#)

PRAC has requested additional data from the marketing authorisation holder.

## Thrombosis with thrombocytopenia syndrome (TTS)

In May 2021, the product information of Vaxzevria was updated with regard to the very rare risk of thrombosis (formation of blood clots in the blood vessels) with thrombocytopenia (low blood platelets) syndrome (TTS)<sup>4</sup>. PRAC is keeping TTS under close monitoring.

As of 27 June 2021, 479 cases of suspected TTS with Vaxzevria were spontaneously reported to EudraVigilance (see section 2) from EU/EEA countries; 100 of these reported a fatal outcome<sup>5,6</sup> (these figures for suspected TTS refer to cases where events of thrombosis and thrombocytopenia were reported in combination; further case ascertainment is required to confirm TTS in these reported cases). About 51.4 million of doses of Vaxzevria had been given to people in the EU/EEA by 20 June 2021<sup>7</sup>.

## 2. 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).

### Case reports of suspected side effects

Collecting reports of medical events and problems that occur following the use of a medicine, and therefore might be side effects, is one of the pillars of the EU safety monitoring system. Healthcare professionals and vaccinated individuals are encouraged to report to their national competent authorities all suspected side effects individuals may have experienced after receiving a vaccine even if it is unclear whether the

<sup>4</sup> See [safety update for Vaxzevria of 11 May 2021](#)

<sup>5</sup> These figures have been calculated excluding cases reported from Northern Ireland (EU reporting requirements for suspected adverse reactions to EudraVigilance apply to Northern Ireland in accordance with the Protocol on Ireland/Northern Ireland).

<sup>6</sup> Source: EudraVigilance. These figures cannot be extracted directly from the public database of suspected adverse reactions, which groups information per type of side effects. As more than one suspected side effect may have been included in a single case report, the total number of side effects will never match the number of individual cases. Similarly, this public database does not provide the total number of cases reported with a fatal outcome.

<sup>7</sup> The [European Centre for Disease Prevention and Control \(ECDC\)](#) collects these exposure data from EU Member States as well as from the additional countries of the European Economic Area (EEA) Norway, Iceland and Liechtenstein.

vaccine was the cause. For more information on how to report, see [Reporting suspected side effects](#).

These spontaneous reports are collected in EudraVigilance, the EU database used for monitoring and analysing suspected side effects. Publicly available information can be accessed via [EudraVigilance – European database of suspected drug reaction reports](#) in all EU/EEA languages. Search for “COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)” to see all suspected side effect cases reported for Vaxzevria.

As of 4 July 2021, a total of 152,250 cases of suspected side effects with Vaxzevria were spontaneously reported to EudraVigilance from EU/EEA countries; 938 of these reported a fatal outcome<sup>8,9</sup>. Around that time, about 58.4 million of doses of Vaxzevria had been given to people in the EU/EEA<sup>10</sup>.

**These reports describe suspected side effects in individuals, i.e. medical events observed following the use of a vaccine. The fact that someone has had a medical issue or died after vaccination does not necessarily mean that this was caused by the vaccine. This may have been caused, for example, by health problems not related to the vaccination.**

The EU regulatory network continuously monitors EudraVigilance to detect any new safety issues. EudraVigilance relies on individual healthcare professionals and patients to report their own experience. The monitoring detects unusual or unexpected patterns in the reports received for further investigation and risk assessment. EMA's detailed assessments take into account all available data from all sources to draw a robust conclusion on the safety of the vaccine. These data include clinical trial results, reports of suspected side effects in EudraVigilance, epidemiological studies monitoring the safety of the vaccine, toxicological investigations and any other relevant information.

## 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

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<sup>9</sup> Source: EudraVigilance. These figures cannot be extracted directly from the public database of suspected adverse reactions, which groups information per type of side effects. As more than one suspected side effect may have been included in a single case report, the total number of side effects will never match the number of individual cases. Similarly, this public database does not provide the total number of cases reported with a fatal outcome.

<sup>10</sup> The [European Centre for Disease Prevention and Control \(ECDC\)](#) collects these exposure data from EU Member States as well as from the additional countries of the European Economic Area (EEA) Norway, Iceland and Liechtenstein.

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.

### 3. 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 had 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 all EU/EEA languages in the [medicine overview](#). This includes information on use in pregnant and breastfeeding women and immunocompromised individuals.

The full [product information](#) with the summary of product characteristics and the package leaflet is also available in all EU/EEA languages.

Medicinal product no longer authorised

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