

11 August 2021

COVID-19 vaccine safety update

COVID-19 VACCINE JANSSEN

Janssen-Cilag International NV

The safety of COVID-19 Vaccine Janssen 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 14 July 2021.

Main outcomes from PRAC's latest safety assessment

Guillain-Barré syndrome has been added to the product information as a very rare side effect.

PRAC recommended updating the product information to include immune thrombocytopenia, dizziness and tinnitus as side effects.

The safety updates are published regularly at [COVID-19 vaccines: authorised](#). All published safety updates for COVID-19 Vaccine Janssen are available at [COVID-19 Vaccine Janssen: safety updates](#).

Since its marketing authorisation in the European Union (EU) on 11 March 2021 until 29 July 2021, around 10.3 million doses of COVID-19 Vaccine Janssen have been administered in the EU/EEA¹.



Around 10.3 million
doses administered in EEA

1. Updates on safety assessments for COVID-19 Vaccine Janssen

PRAC assessed new safety data, including the latest Monthly Summary Safety Report (MSSR)² from the marketing authorisation holder and data reported by patients and healthcare professionals to EudraVigilance (see section 2), during its meetings on 22 July and 5 August 2021.

Guillain-Barré syndrome

Guillain-Barré syndrome (GBS) was included in the product information as a very rare side effect of COVID-19 Vaccine Janssen, together with a warning to raise awareness among healthcare professionals and people taking the vaccine.

GBS is a rare neurological disorder in which the body's immune system damages nerve cells which can result in pain, numbness and muscle weakness, progressing to paralysis in the most severe cases. Most people eventually fully recover even from the most severe symptoms, while some may continue to have some degree of weakness.

PRAC assessed the available evidence, including cases reported to EudraVigilance (see section 2) and information from the scientific literature. PRAC assessed 108 cases of GBS reported worldwide as of 30 June 2021, when over 21 million people had received the vaccine globally. There was one reported death among these cases.

Although cases of GBS after vaccination with COVID-19 Vaccine Janssen have been reported very rarely, healthcare professionals should be alert to signs and symptoms of GBS, in view of the seriousness of this condition, to allow for early diagnosis, supportive care and treatment.

¹ The [European Centre for Disease Prevention and Control \(ECDC\)](https://ecdc.europa.eu/en/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.

² 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).

Vaccinated people are advised to seek immediate medical attention if they develop signs and symptoms suggestive of GBS, such as:

- Weakness in the limbs, chest or face
- Double vision or difficulty moving eyes
- Difficulty swallowing, speaking, or chewing
- Coordination problems and unsteadiness
- Difficulty walking
- Difficulty breathing
- Tingling sensations in the hands and feet
- Problems with bladder control and bowel function.

Immune thrombocytopenia

PRAC recommended updating the product information of COVID-19 Vaccine Janssen to include immune thrombocytopenia (ITP) as a side effect, together with a warning to alert healthcare professionals and people taking the vaccine.

ITP is a condition in which the immune system mistakenly attacks and destroys blood cells called platelets that are needed for normal blood clotting.

PRAC assessed the available evidence, including scientific literature and cases reported to EudraVigilance (see section 2), to the Vaccine Adverse Event Reporting System (VAERS) in the United States³ and to the marketing authorisation holder's global safety database. The MSSR included 120 worldwide cases of suspected ITP by 18 June 2021, of which 27 cases were reported from clinical trials and 93 were reported spontaneously from vaccination campaigns; of these, 4 cases had a fatal outcome.

As of 30 June 2021, over 21 million people had received the vaccine globally.

Other events: dizziness and tinnitus

PRAC concluded that dizziness and tinnitus (ringing or other noises in one or both ears) should be added to the product information as side effects of COVID-19 Vaccine Janssen.

In reaching this conclusion, PRAC took into consideration available evidence. This included an analysis of 1,183 worldwide cases of dizziness identified from spontaneous reports received through 31 May 2021.

Regarding tinnitus, 6 cases observed in clinical trials and 108 worldwide

³ See [Vaccine Adverse Event Reporting System \(VAERS\) \(hhs.gov\)](https://www.hhs.gov/vaers/)

cases identified by the marketing authorisation holder, reported through 18 May 2021, during monitoring spontaneous reports were investigated.

As of 30 June 2021, over 21 million people had received the vaccine globally.

Menstrual disorders

PRAC discussed reported cases of menstrual disorders occurring after vaccination against COVID-19. No causal association between COVID-19 vaccines and menstrual disorders has been established so far.

Menstrual disorders are very common in the general population and can occur without an underlying medical condition. Causes can range from stress and tiredness to conditions such as fibroids and endometriosis. Women experiencing unexpected vaginal bleeding (e.g. in postmenopausal women) or who are concerned about prolonged or severe menstrual disturbances may want to seek medical advice.

The marketing authorisation holders for all COVID-19 vaccines authorised in the EU have been requested to provide further data as part of the MSSRs. PRAC will review all available evidence, including reports of suspected side effects and scientific literature, and will continue monitoring the issue.

2. How safety is monitored

As for all COVID-19 vaccines, relevant new information emerging on COVID-19 Vaccine Janssen 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 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 JANSSEN (AD26.COV2.S)” to

see all suspected side effect cases reported for COVID-19 Vaccine Janssen.

As of 29 July 2021, a total of 15,371 cases of suspected side effects with COVID-19 Vaccine Janssen were spontaneously reported to EudraVigilance from EU/EEA countries; 95 of these reported a fatal outcome^{4,5}. By the same date, about 10.3 million doses of COVID-19 Vaccine Janssen had been given to people in the EU/EEA⁶.

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 COVID-19 Vaccine Janssen will continue to provide results from ongoing clinical trials. 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 COVID-19 Vaccine Janssen, see the [risk management plan](#).

A [paediatric investigation plan](#) (PIP) for COVID-19 Vaccine Janssen is in place. This describes how the company will collect data on the vaccine's efficacy and safety for its potential use in children.

⁴ 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).

⁵ 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.

⁶ 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 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 COVID-19 Vaccine Janssen

COVID-19 Vaccine Janssen is a vaccine that was authorised in the EU on 11 March 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.

COVID-19 Vaccine Janssen 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 COVID-19 Vaccine Janssen 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 27,000 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 COVID-19 Vaccine Janssen are usually mild or moderate and get better within a few days after vaccination.

More information on how COVID-19 Vaccine Janssen 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

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