



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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COVID-19 vaccine safety update

COVID-19 VACCINE JANSSEN

Janssen-Cilag International NV

Unusual blood clots in combination with low blood platelet levels have been identified as a very rare side effect of COVID-19 Vaccine Janssen.

Vaccinated persons should seek immediate medical attention if symptoms of blood clotting occur, to help avoid complications.

There are no recommended changes to the product information regarding the use of this vaccine; COVID-19 Vaccine Janssen is effective in preventing COVID-19.

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 COVID-19 Vaccine Janssen are available at [COVID-19 Vaccine Janssen: safety updates](#).

This safety update follows the last update of 14 April 2021.

The use of COVID-19 Vaccine Janssen in vaccination campaigns in the EU/EEA¹ was temporarily postponed by the marketing authorisation holder.

1. Updates on safety of COVID-19 Vaccine Janssen

At its meeting on 20 April 2021, PRAC assessed the following in relation to:

Emboic and thrombotic events with a focus on thrombosis with thrombocytopenia

PRAC assessed events of thrombosis (blood clots obstructing blood vessels) occurring together with thrombocytopenia (low blood platelets) reported after vaccination with COVID-19 Vaccine Janssen.

Taking into account all available evidence, including knowledge gained from the recent PRAC assessment of similar adverse events for Vaxzevria (previously COVID-19 Vaccine AstraZeneca)², PRAC concluded that the product information for COVID-19 Vaccine Janssen should be updated to specify thrombosis with thrombocytopenia as a new very rare side effect. Furthermore, a warning should be included in the product information to make healthcare professionals and those being vaccinated aware of these very rare events and of their symptoms.

People vaccinated with COVID-19 Vaccine Janssen should seek immediate medical attention and inform healthcare professionals of their recent vaccination if they experience severe or persistent headache, blurred vision, shortness of breath, chest pain, persistent abdominal pain, leg swelling, unexplained skin bruising or tiny blood spots under the skin beyond the site of vaccination appearing a few days after vaccination.

Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia and inform vaccinated people accordingly. Thrombosis in combination with thrombocytopenia requires specialised clinical management. Healthcare professionals should consult applicable guidance and specialists in haematology or coagulation to diagnose and treat this condition. Early recognition of the signs and timely initiation of treatment can help recovery and avoid complications.

The PRAC assessment included eight cases of such events, reported for COVID-19 Vaccine Janssen from clinical trials (1 case) and vaccination campaigns (7 cases) in the United States (US). More than 27,000 persons had been vaccinated in clinical trials and about 7 million people in the US

¹ The European Economic Area (EEA) includes the Member States of the European Union (EU) as well as the additional countries Norway, Iceland and Liechtenstein.

² See EMA's [COVID-19 vaccine safety update for Vaxzevria: 14 April 2021](#)

vaccination campaigns³. The allocated frequency category 'very rare (occurring in less than 1 in 10,000 persons)' is the category with the lowest frequency defined for regulatory labelling of any side effect in a product information.

The reported cases of thrombosis occurring with thrombocytopenia, and sometimes with bleeding, included severe venous thromboses, mostly in unusual sites such as cerebral venous sinus thrombosis (CVST) (where blood clots in the brain's venous sinuses prevent blood from draining out of the brain) and splanchnic vein thrombosis (which involves one or more veins in the abdomen, e.g. in liver, bowel and spleen), as well as arterial thromboses.

These cases occurred within the first three weeks following vaccination, and mostly in women under 60 years of age; one had a fatal outcome. Based on the available data, the pathophysiological mechanism leading to such events could not yet be established, nor could specific risk factors be identified⁴.

Further clarification and data have been requested from the marketing authorisation holder to support PRAC's continued close monitoring. Studies investigating embolic and thrombotic events are already in place as part of the [risk management plan](#) approved at the time of the marketing authorisation.

A direct healthcare professional communication (DHPC) will be sent out and published to raise awareness among healthcare professionals of the updates to the product information.

The use of COVID-19 Vaccine Janssen in EU Member States should follow official recommendations of the national health authorities.

2. 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 have been given the vaccine in clinical trials.

³ See [CDC and FDA Joint Statement on Johnson & Johnson COVID-19 Vaccine of 13 April 2021](#)

⁴ See [EMA Public Health Communication of 20 April 2021](#)

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 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 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).

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 JANSSEN (AD26.COV2.S)” to see all suspected side effects reported for COVID-19 Vaccine Janssen 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 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.

In addition, EMA is coordinating [observational studies](#) in 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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