14 April 2021

COVID-19 vaccine safety update

COVID-19 VACCINE JANSSEN

Janssen-Cilag International NV

The latest safety data for this vaccine, collected from vaccination campaigns outside the EU/EEA, is presented in this safety update.

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

Safety updates provide information about the assessments of emerging worldwide data since marketing authorisation for COVID-19 vaccines. The assessments are carried out by EMA's safety committee (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 is the first update after the marketing authorisation in the European Union (EU).

The use of COVID-19 Vaccine Janssen in vaccination campaigns in the EU/EEA[1] has not yet started.

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

1. Updates on safety of COVID-19 Vaccine Janssen

At its meeting held 6 to 9 April 2021, PRAC assessed the following in relation to:

Embolic and thrombotic events with a focus on thrombosis with thrombocytopenia

PRAC started an assessment of embolic and thrombotic events (blood clots obstructing blood vessels), following a small number of reported cases of suspected serious, unusual types of thrombosis together with thrombocytopenia (low blood platelets).

Based on the clinical trial data at the time of marketing authorisation, venous thromboembolism was already included in the risk management plan for COVID-19 Vaccine Janssen as a potential, but not confirmed, risk to be monitored and studied.

PRAC requested a review from the marketing authorisation holder. PRAC is also collecting further information to assess whether COVID-19 Vaccine Janssen may cause embolic and thrombotic events and to decide whether the product information should be updated. A causal relationship between these reported events and COVID-19 Vaccine Janssen has so far not been established[2].

Within its framework of international collaboration, EMA is engaged in mutual exchange with the US Food and Drug Administration (FDA) on the matter.

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

[2] See Meeting Highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 6-9 April 2021

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 21,000 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 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.

Use of COVID-19 Vaccine Janssen in the EU/EEA following marketing authorisation has not yet started; EudraVigilance therefore does currently not contain any cases of suspected side effects reported from vaccination campaigns in the EU/EEA.

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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