EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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COVID-19 vaccine safety update

COVID-19 VACCINE JANSSEN

Janssen-Cilag International NV

Individuals diagnosed with thrombocytopenia within 3 weeks after vaccination with COVID-19 Vaccine Janssen should be actively investigated for signs of thrombosis; similarly, individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia.

COVID-19 Vaccine Janssen is effective in preventing COVID-19.

This safety update follows the last update of 22 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 COVID-19 Vaccine Janssen are available at COVID-19 Vaccine Janssen: safety updates.

Since the marketing authorisation in the European Union (EU) on 11 March 2021 until 6 May 2021, more than 500,000 doses of COVID-19 Vaccine Janssen have been administered in the EU/EEA[1].

1. Updates on safety of COVID-19 Vaccine Janssen

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

Embolic and thrombotic events with a focus on thrombosis with thrombocytopenia syndrome (TTS)

PRAC concluded that the following should be added to the product information for COVID-19 Vaccine Janssen:

- advice that individuals diagnosed with thrombocytopenia (low blood platelets) within 3 weeks of vaccination with COVID-19 Vaccine Janssen should be actively investigated for signs of thrombosis (formation of blood clots in the vessels), and similarly individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia;

- addition of leg pain, seizures (fits) and mental status change as possible signs and symptoms of thrombosis with thrombocytopenia syndrome (TTS) (in addition to the signs and symptoms already included in the product information: severe or persistent headache, blurred vision, unexplained skin bruising beyond the site of vaccination which appear a few days after vaccination, shortness of breath, chest pain, leg swelling, or persistent abdominal pain).

These additions follow the update to the product information of 22 April 2021 regarding TTS[3].

Further, the risk management plan (RMP) for COVID-19 Vaccine Janssen will be updated, and the marketing authorisation holder will provide a plan

[1] 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.
[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).
[3] See Safety Update for COVID-19 Vaccine Janssen of 22 April 2021

within the RMP with the aim to further study these very rare events of TTS, including the possible underlying mechanisms[4].

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.

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

[4] See Meeting Highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 3-6 May 2021

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 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.

European Medicines Agency
Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact
Telephone +31 (0)88 781 6000

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