EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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COVID-19 Vaccine Janssen (*COVID-19 vaccine (Ad26.COV2-S [recombinant])*)

What is COVID-19 Vaccine Janssen and what is it used for?

COVID-19 Vaccine Janssen is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 18 years and older. COVID-19 is caused by SARS-CoV-2 virus.

COVID-19 Vaccine Janssen is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making a protein found on SARS-CoV-2.

COVID-19 Vaccine Janssen does not contain SARS-CoV-2 itself and cannot cause COVID-19.

Detailed information about this vaccine is available in the product information [insert link], which includes the package leaflet.

How is COVID-19 Vaccine Janssen used?

COVID-19 Vaccine Janssen is given as a single injection, usually into the muscle of the upper arm.

Arrangements for the supply of the vaccine will be the responsibility of national authorities. For more information about using COVID-19 Vaccine Janssen, see the package leaflet or consult a healthcare professional.

How does COVID-19 Vaccine Janssen work?

COVID-19 Vaccine Janssen works by preparing the body to defend itself against COVID-19. It is made up of another virus (an adenovirus) that has been modified to contain the gene for making the SARS-CoV-2 spike protein. This is a protein on the SARS-CoV-2 virus which it needs to enter the body's cells.

The adenovirus passes the SARS-CoV-2 gene into the vaccinated person's cells. The cells can then use the gene to produce the spike protein. The person's immune system will recognise the spike protein as foreign and produce antibodies and activate T cells (white blood cells) to target it.

Later, if the person comes into contact with SARS-CoV-2 virus, the person's immune system will recognise the spike protein on the virus and be ready to defend the body against it.

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The adenovirus in the vaccine cannot reproduce and does not cause disease.

What benefits of COVID-19 Vaccine Janssen have been shown in studies?

Results from a clinical trial involving people in the United States, South Africa and Latin American countries found that COVID-19 Vaccine Janssen was effective at preventing COVID-19 in people from 18 years of age. This study involved over 44,000 people. Half received a single dose of the vaccine and half were given placebo (a dummy injection). People did not know if they had been given COVID-19 Vaccine Janssen or placebo.

The trial found a 67% reduction in the number of symptomatic COVID-19 cases after 2 weeks in people who received COVID-19 Vaccine Janssen (116 cases out of 19,630 people) compared with people given placebo (348 of 19,691 people). This means that the vaccine had a 67% efficacy at 2 weeks. A similar efficacy was seen at 4 weeks.

Can people who have already had COVID-19 be vaccinated with COVID-19 Vaccine Janssen?

There were no additional side effects in 2,151 people who received COVID-19 Vaccine Janssen in the trials and had previously had COVID-19.

There were not enough data from the trials to conclude on how well COVID-19 Vaccine Janssen works for people who have already had COVID-19.

Can COVID-19 Vaccine Janssen reduce transmission of the virus from one person to another?

The effect of COVID-19 Vaccine Janssen on the spread of the SARS-CoV-2 virus in the community is not yet known. It is not yet known how much vaccinated people may still be able to carry and spread the virus.

How long does protection from COVID-19 Vaccine Janssen last?

Protection with COVID-19 Vaccine Janssen starts around 14 days after vaccination but it is not currently known how long protection continues. The people vaccinated in the clinical trials will continue to be followed for 2 years to gather more information on the duration of protection.

Can children be vaccinated with COVID-19 Vaccine Janssen?

COVID-19 Vaccine Janssen is not currently recommended for use in children. EMA has agreed with the company on a plan to conduct trials involving children at a later stage.

Can immunocompromised people be vaccinated with COVID-19 Vaccine Janssen?

There are no data on immunocompromised people (people with weakened immune systems). Although immunocompromised people may not respond as well to the vaccine, there are no particular safety concerns. Immunocompromised people can still be vaccinated as they may be at higher risk from COVID-19.

Can pregnant or breast-feeding women be vaccinated with COVID-19 Vaccine Janssen?

Animal studies do not show any harmful effects of COVID-19 Vaccine Janssen in pregnancy. However, data on the use of COVID-19 Vaccine Janssen during pregnancy are very limited.

There are no studies of COVID-19 Vaccine Janssen on breast-feeding but no risk from breast-feeding is expected.

The decision on whether to use the vaccine in pregnant women should be made in close consultation with a healthcare professional after considering the benefits and risks.

Can people with allergies be vaccinated with COVID-19 Vaccine Janssen?

People who have an allergy to one of the components of the vaccine listed in section 6 of the package leaflet should not receive the vaccine.

Allergic reactions (hypersensitivity) have occurred in people receiving the vaccine. One case of anaphylaxis (severe allergic reaction) has occurred in an ongoing study. As for all vaccines, COVID-19 Vaccine Janssen should be given under close medical supervision, with the appropriate medical treatment available in case of allergic reactions.

How well does COVID-19 Vaccine Janssen work for people of different ethnicities and genders?

The clinical trials included people of different ethnicities and genders. The vaccine worked across genders and ethnic groups.

What are the risks associated with COVID-19 Vaccine Janssen?

The most common side effects with COVID-19 Vaccine Janssen in the trials were usually mild or moderate and got better within 1 or 2 days after vaccination. The most common side effects are pain at the injection site, headache, tiredness, muscle pain and nausea. They affected more than 1 in 10 people.

Coughing, joint pain, fever, chills and redness and swelling at injection side occurred in less than 1 in 10 people. Sneezing, tremor, throat pain, rash, sweating, muscle weakness, pain in the arms and legs, backache, weakness and feeling generally unwell occurred in less than 1 in 100 people. Rare side effects (that occurred in less than 1 in 1,000 people) are hypersensitivity (allergy) and itchy rash.

Allergic reactions, including one case of anaphylaxis (severe allergic reaction), have occurred in people receiving the vaccine. As for all vaccines, COVID-19 Vaccine Janssen should be given under close supervision with appropriate medical treatment available.

Why has EMA recommended the authorisation of COVID-19 Vaccine Janssen?

COVID-19 Vaccine Janssen offers a good level of protection against COVID-19 which is vital during the current pandemic. The main trial showed that the vaccine has around 67% efficacy. Most side effects are mild to moderate in severity and last only a few days.

The European Medicines Agency therefore decided that COVID-19 Vaccine Janssen's benefits are greater than its risks and it can be recommended for authorisation in the EU.

COVID-19 Vaccine Janssen has been recommended for 'conditional marketing authorisation'. This means that there is more evidence to come about the vaccine (see below), which the company is required to provide. The Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for COVID-19 Vaccine Janssen?

Since COVID-19 Vaccine Janssen has been recommended for conditional marketing authorisation, the company that markets the vaccine will provide results from ongoing clinical trials. These trials and additional studies will provide information on how long protection lasts, the vaccine's effectiveness against new variants of the virus, how well it protects older people, people of different ethnicities, immunocompromised people, children and pregnant women, whether it prevents asymptomatic cases, and the effects and timing of a second dose of the vaccine.

In addition, independent studies of COVID-19 vaccines coordinated by EU authorities will also give more information on the vaccine's long-term safety and benefit in the general population.

The company will also carry out studies to provide additional assurance on the pharmaceutical quality and testing of the vaccine as the manufacturing continues to be scaled up.

What measures are being taken to ensure the safe and effective use of COVID-19 Vaccine Janssen?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of COVID-19 Vaccine Janssen have been included in the summary of product characteristics and the package leaflet.

A risk management plan for COVID-19 Vaccine Janssen is also in place and contains important information about the vaccine's safety, how to collect further information and how to minimise any potential risks. A summary of the RMP [insert link] is available.

Safety measures will be implemented for COVID-19 Vaccine Janssen in line with the EU safety monitoring plan for COVID-19 vaccines to ensure that new safety information is rapidly collected and analysed. The company that markets COVID-19 Vaccine Janssen will provide monthly safety reports.

As for all medicines, data on the use of COVID-19 Vaccine Janssen are continuously monitored. Suspected side effects reported with COVID-19 Vaccine Janssen are carefully evaluated and any necessary action taken to protect patients.

Other information about COVID-19 Vaccine Janssen

COVID-19 Vaccine Janssen was recommended by EMA's human medicines committee (CHMP) on 11 March 2021 for a conditional marketing authorisation valid throughout the EU. The European Commission will issue a decision shortly.

Detailed recommendations for the use of this product are described in the product information [insert link], which will be available in all official European Union languages after a decision on the marketing authorisation has been issued by the European Commission.