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Jcovden[1] (*COVID-19 vaccine (Ad26.COV2-S [recombinant])*)

An overview of Jcovden and why it is authorised in the EU

What is Jcovden and what is it used for?

Jcovden 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.

Jcovden 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.

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

How is Jcovden used?

Jcovden is given as an injection, usually into the muscle of the upper arm.

A booster dose may be given at least 2 months after the first dose of Jcovden in people aged 18 years and older. A booster dose may also be given after a primary vaccination course with an mRNA or adenoviral vector vaccine. The timing of a Jcovden booster dose depends on when a booster would normally be given for such vaccines.

The vaccine should be used according to official recommendations issued at national level by public health bodies. For more information about using Jcovden, see the package leaflet or consult a healthcare professional.

How does Jcovden work?

Jcovden 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 surface of the SARS-CoV-2 virus which the virus needs to enter the body's cells.

[1] Previously known as COVID-19 Vaccine Janssen

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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 the 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.

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

What benefits of Jcovden have been shown in studies?

Results from a clinical trial involving people in the United States, South Africa and Latin American countries found that Jcovden 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 Jcovden or placebo.

The trial found a 67% reduction in the number of symptomatic COVID-19 cases after 2 weeks in people who received Jcovden (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.

Further data showed a rise in antibody levels when a booster dose was given after completion of a primary course with Jcovden, an mRNA vaccine, or another adenoviral vector vaccine in people from 18 years of age.

Can children be vaccinated with Jcovden?

Jcovden is not currently authorised for use in children.

Can immunocompromised people be vaccinated with Jcovden?

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 Jcovden?

Animal studies do not show any harmful effects of Jcovden in pregnancy. However, data on the use of Jcovden during pregnancy are very limited. There are no studies of Jcovden 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 Jcovden?

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, including rare cases of anaphylaxis (severe allergic reaction). As for all vaccines, Jcovden should be given under close medical supervision, with the appropriate medical treatment available in case of allergic reactions.

How well does Jcovden 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 Jcovden?

For the full list of side effects and restrictions with Jcovden, see the package leaflet.

The most common side effects with Jcovden are usually mild or moderate and get better within 1 or 2 days after vaccination.

The most common side effects are pain at the injection site, tiredness, headache, muscle pain and nausea. They may affect more than 1 in 10 people.

Fever, chills, as well as redness and swelling at injection site may affect up to 1 in 10 people. Dizziness, shaking, coughing, mouth and throat pain, sneezing, diarrhoea, vomiting, rash, joint pain, muscle weakness, backache, pain in the arms and legs, weakness and feeling generally unwell may affect up to 1 in 100 people. Rare side effects (which may affect up to 1 in 1,000 people) are lymphadenopathy (enlarged lymph nodes), itchy rash, hypersensitivity (allergy), paraesthesia (unusual sensations like numbness, tingling or pins and needles), hypoesthesia (reduced sensation to touch, pain and temperature), facial paralysis, tinnitus (ringing or buzzing in the ears), venous thromboembolism (formation of blood clots in veins) and sweating.

For booster vaccinations, the number and severity of reactions tend to be higher when people have previously been vaccinated with a vaccine other than Jcovden compared to people who have completed a primary course with Jcovden.

Thrombosis (formation of blood clots in the blood vessels) in combination with thrombocytopenia (low levels of blood platelets), known as TTS (thrombosis with thrombocytopenia syndrome), and Guillain-Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells) may affect up to 1 in 10,000 people.

Allergic reactions, including anaphylaxis (severe allergic reaction), have occurred in people receiving the vaccine. As for all vaccines, Jcovden should be given under close supervision with appropriate medical treatment available.

A very small number of cases of immune thrombocytopenia (a condition in which the immune system mistakenly targets blood platelets, reducing their levels and affecting normal blood clotting), capillary leak syndrome (fluid leakage from small blood vessels causing tissue swelling and a drop in blood pressure), cutaneous small vessel vasculitis (inflammation of blood vessels in the skin), transverse myelitis (a neurological condition characterised by an inflammation in the spinal cord), myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) have occurred with Jcovden.

Jcovden must not be given to people who have previously had capillary leak syndrome; it must also not be given to people who have had TTS following vaccination with any COVID-19 vaccine.

Why is Jcovden authorised in the EU?

Jcovden offers a good level of protection against COVID-19 which is critical 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 Jcovden's benefits are greater than its risks and it can be authorised for use in the EU.

Jcovden was originally given 'conditional authorisation' because there was more evidence to come about the vaccine. The company has provided comprehensive information, including data regarding its safety and efficacy, confirming the findings from earlier studies previously submitted. In addition, the company has completed all requested studies on the pharmaceutical quality of the vaccine. As a result, the conditional authorisation has been switched to a standard one.

What measures are being taken to ensure the safe and effective use of Jcovden?

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

A risk management plan (RMP) for Jcovden 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 is available.

Safety measures for Jcovden are implemented 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 Jcovden will provide regular safety reports.

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

Other information about Jcovden

COVID-19 Vaccine Janssen received a conditional marketing authorisation valid throughout the EU on 11 March 2021. The name of the vaccine was changed to Jcovden on 28 April 2022. The conditional marketing authorisation was switched to a standard marketing authorisation on 9 January 2023.

More information about the COVID-19 vaccines is available on the COVID-19 vaccines key facts page.

Further information on Jcovden can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/jcovden

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