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VidPrevtyn Beta *(SARS-CoV-2 prefusion Spike delta TM protein, recombinant (B.1.351 strain))*

An overview of VidPrevtyn Beta and why it is authorised in the EU

What is VidPrevtyn Beta and what is it used for?

VidPrevtyn Beta is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 18 years and older. It can be used once as a booster in people who have already received an mRNA or adenoviral vector COVID-19 vaccine.

VidPrevtyn Beta contains a version of a protein found on the surface of SARS-CoV-2 (the spike protein of the virus that causes COVID-19), which has been produced in the laboratory.

How is VidPrevtyn Beta used?

VidPrevtyn Beta is given as an injection, usually in the muscle of the upper arm. It can be given once as a booster, at least 4 months after a previous mRNA or adenoviral vector COVID-19 vaccine.

Arrangements for the supply of the vaccine will be the responsibility of national authorities.

For more information about using VidPrevtyn Beta, see the package leaflet or consult a healthcare professional.

How does VidPrevtyn Beta work?

VidPrevtyn Beta works by preparing the body to defend itself against COVID-19. The vaccine contains a version produced in the laboratory of the spike protein found on the surface of the SARS-CoV-2 Beta variant. It also contains an 'adjuvant', a substance to help strengthen the immune response to the vaccine.

When a person is given the vaccine, their immune system will identify the protein as foreign and produce natural defences — antibodies and T cells — against it. If, later on, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the spike protein on the virus and be prepared to attack it. The antibodies and immune cells can protect against COVID-19 by working together to kill the virus, prevent its entry into the body's cells and destroy infected cells.

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 An agency of the European Union

What benefits of VidPrevtyn Beta have been shown in studies?

The benefits of VidPrevtyn Beta were assessed in two immunobridging studies which compared the immune response triggered by VidPrevtyn Beta with that triggered by an authorised comparator vaccine proven to be effective against the disease.

The first trial involved 162 people aged 18 years and older, who were given a booster of VidPrevtyn Beta or the comparator vaccine (the originally authorised Comirnaty vaccine targeting the spike protein of the original SARS-CoV-2 strain). The study showed that a booster dose of VidPrevtyn Beta triggers a higher production of antibodies against the SARS-CoV-2 Omicron BA.1 subvariant than Comirnaty.

In a second main study, a booster injection with VidPrevtyn Beta restored immunity against different SARS-CoV-2 virus variants in 627 people aged 18 and older who had previously completed a primary vaccination course with an mRNA vaccine (Comirnaty or Spikevax) or an adenoviral vector vaccine (Vaxzevria or Jcovden).

Can children be vaccinated with VidPrevtyn Beta?

VidPrevtyn Beta is not currently recommended for people below 18 years of age. EMA has agreed with the company on a plan to assess the vaccine in children at a later stage.

Can immunocompromised people be vaccinated with VidPrevtyn Beta?

VidPrevtyn Beta has not been studied in 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 VidPrevtyn Beta?

Animal studies do not show any harmful effects in pregnancy; however, data on the use of VidPrevtyn Beta during pregnancy are very limited.

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.

Although there are no studies on breast-feeding, no risk for breast-feeding is expected.

Can people with allergies be vaccinated with VidPrevtyn Beta?

People who already know they have an allergy to one of the components of the vaccine listed in section 6 of the package leaflet, or to the substance octylphenol ethoxylate, should not receive the vaccine.

Allergic reactions (hypersensitivity) may occur in people receiving the vaccine. Therefore, as for all vaccines, VidPrevtyn Beta should be given under close medical supervision, with the appropriate medical treatment available.

How well does VidPrevtyn Beta work for people of different ethnicities and genders?

The immune response triggered by the vaccine in the main study was maintained across genders. There is no reason to suggest that the immune response induced by VidPrevtyn Beta will vary across ethnicities.

What are the risks associated with VidPrevtyn Beta?

The most common side effects with VidPrevtyn Beta (which may affect more than 1 in 10 people) are pain at the injection site, headache, muscle or joint pain, feeling generally unwell and chills. Nausea (feeling sick), diarrhoea, fever, tiredness, reddening or swelling at the injection site may affect less than 1 in 10 people. Lymphadenopathy (enlarged lymph nodes), and itching, bruising or a warm sensation at the injection site may affect less than 1 in 100 people.

Allergic reactions may occur with VidPrevtyn Beta. As for all vaccines, VidPrevtyn Beta should be given under close supervision with appropriate medical treatment available.

Why is VidPrevtyn Beta authorised in the EU?

Based on data comparing the immune response triggered by VidPrevtyn Beta with that triggered by an authorised COVID-19 vaccine, the European Medicines Agency concluded that VidPrevtyn Beta is expected to be at least as effective as the comparator at protecting against the disease in people from 18 years of age. Regarding safety, most side effects are mild to moderate in severity and are gone within a few days.

The Agency therefore decided that VidPrevtyn Beta's benefits are greater than its risks and that it can be authorised for use in the EU.

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

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

A risk management plan for VidPrevtyn Beta 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.

Safety measures will be implemented for VidPrevtyn Beta 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 VidPrevtyn Beta will provide monthly safety reports.

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

Other information about VidPrevtyn Beta

VidPrevtyn Beta received a marketing authorisation valid throughout the EU on 10 November 2022.

Further information on VidPrevtyn Beta can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/vidprevtyn-beta

This overview was last updated in 11-2022.