



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## VidPrevtyl Beta

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

### What is VidPrevtyl Beta and what is it used for?

VidPrevtyl 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.

VidPrevtyl 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. It also contains an 'adjuvant', a substance to help strengthen the immune responses to the vaccine.

Detailed information about this vaccine is available in the [product information](#), which includes the package leaflet.

### How is VidPrevtyl Beta used?

VidPrevtyl 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 VidPrevtyl Beta, see the package leaflet or consult a healthcare professional.

### How does VidPrevtyl Beta work?

VidPrevtyl 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 responses 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.

### **What benefits of VidPrevtyl Beta have been shown in studies?**

The benefits of VidPrevtyl Beta were assessed in two immunobridging studies which compared the immune response triggered by VidPrevtyl 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 VidPrevtyl 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 VidPrevtyl 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 VidPrevtyl 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 VidPrevtyl Beta?**

VidPrevtyl 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 VidPrevtyl Beta?**

VidPrevtyl 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 VidPrevtyl Beta?**

Animal studies do not show any harmful effects in pregnancy; however, data on the use of VidPrevtyl 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 VidPrevtyl 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, VidPrevtyl Beta should be given under close medical supervision, with the appropriate medical treatment available.

## **How well does VidPrevtyl 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 VidPrevtyl Beta will vary across ethnicities.

## **What are the risks associated with VidPrevtyl Beta?**

The most common side effects with VidPrevtyl 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 VidPrevtyl Beta. As for all vaccines, VidPrevtyl Beta should be given under close supervision with appropriate medical treatment available.

## **Why has EMA recommended the authorisation of VidPrevtyl Beta?**

Based on data comparing the immune response triggered by VidPrevtyl Beta with that triggered by an authorised COVID-19 vaccine, EMA concluded that VidPrevtyl 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 VidPrevtyl Beta's benefits are greater than its risks and that it can be recommended for authorisation in the EU.

## **What measures are being taken to ensure the safe and effective use of VidPrevtyl Beta?**

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

A risk management plan (RMP) for VidPrevtyl 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. A [summary of the RMP](#) is available.

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

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

## **Other information about VidPrevtyl Beta**

VidPrevtyl Beta was recommended by EMA's human medicines committee (CHMP) on 10 November 2022 for a 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](#), which will be available in all official European Union languages after a decision on the marketing authorisation has been issued by the European Commission.

Medicinal product no longer authorised