Package leaflet: Information for the User

VidPrevtyn Beta, solution and emulsion for emulsion for injection
COVID-19 vaccine (recombinant, adjuvanted)

Is this leaflet hard to see or read? Phone 0800 035 2525 for help

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What VidPrevtyn Beta is and what it is used for

VidPrevtyn Beta is a vaccine used for preventing COVID-19.
VidPrevtyn Beta is given to adults who previously received either mRNA or adenoviral vector COVID-19 vaccine.

The vaccine stimulates the immune system (the body's natural defences) to produce specific antibodies that work against the virus, giving protection against COVID-19. None of the ingredients in this vaccine can cause COVID-19.

2. What you need to know before you receive VidPrevtyn Beta

Do not use VidPrevtyn Beta:
If you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6);
If you are allergic to octylphenol ethoxylate, a substance that is used in the manufacturing process. Small amounts of this substance may remain after manufacturing.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given the vaccine if:
- you have ever had a severe allergic reaction after any other vaccine injection or after you were given VidPrevtyn Beta in the past;
- you have ever fainted following any needle injection;
- you have a severe illness or infection with a high temperature (over 38°C). However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood clots.
- you have a weakened immune system (immunodeficiency) or you are using medicines that weaken the immune system (such as high-dose corticosteroids or cancer medicines).

As with any vaccine, VidPrevtyn Beta may not fully protect all those who receive it. It is not known how long you will be protected.

Children and adolescents
VidPrevtyn Beta is not recommended for children aged under 18 years. Currently there is no information available on the use of VidPrevtyn Beta in children and adolescents younger than 18 years of age.

Other medicines and VidPrevtyn Beta
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines or vaccines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before you receive this vaccine.

Driving and using machines
Some of the side effects of VidPrevtyn Beta mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

VidPrevtyn Beta contains sodium and potassium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.
This medicine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

3. How VidPrevtyn Beta is given

Your doctor, pharmacist or nurse will inject the vaccine into a muscle, usually in your upper arm.

You will receive one injection.
It is recommended that you receive VidPrevtyn Beta once as a booster dose at minimum 4 months following the prior vaccination series with either mRNA or adenoviral vector COVID-19 vaccine.

After the injection your doctor, pharmacist or nurse will watch over you for around 15 minutes to monitor for signs of an allergic reaction.

If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Most of the side effects occur within 3 days of getting the vaccine and go away within a few days of appearing. If symptoms persist, contact your doctor, pharmacist or nurse.

Get **urgent** medical attention if you get symptoms of a severe allergic reaction shortly after vaccination. Such symptoms may include:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of your lips, face, or throat

- itchy swelling under the skin (hives) or rash
- feeling sick (nausea) or vomiting
- stomach pain.

The following side effects may occur with VidPrevtyn Beta:
Side effects which may affect up to 1 in 100 people may not have all been detected in the clinical studies done to date.

Very common (may affect more than 1 in 10 people):
- Headache
- Muscle pain
- Joint pain
- Feeling unwell
- Chills
- Pain where the vaccine is injected

Common (may affect up to 1 in 10 people):
- Fever (≥ 38.0ºC)
- Tiredness
- Feeling sick (nausea)
- Diarrhoea
- Redness or swelling where the vaccine is injected

Uncommon (may affect up to 1 in 100 people):
- Enlarged lymph nodes
- Itching, bruising or warmth where the vaccine is injected.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. If you are concerned about a side effect it can be reported directly via the Yellow Card reporting site www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store and include batch/lot number if available. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store VidPrevtyn Beta

Keep this vaccine out of the sight and reach of children.

Information about storage, use and handling are described in the section intended for healthcare professionals at the end of the package leaflet.

6. Contents of the pack and other information

What VidPrevtyn Beta contains
- There are two multidose vials (antigen vial and adjuvant vial) that must be mixed before use. After mixing, the vaccine vial contains 10 doses of 0.5 mL.
- One dose (0.5 mL) contains 5 micrograms of recombinant SARS-CoV-2 spike protein antigen (B.1.351 strain).
- AS03 is included in this vaccine as an adjuvant to enhance production of specific antibodies. This adjuvant contains squalene (10.69 milligrams), DL-α-tocopherol (11.86 milligrams) and polysorbate 80 (4.86 milligrams).
- The other ingredients are: sodium dihydrogen phosphate monohydrate, disodium phosphate dodecahydrate, sodium chloride, polysorbate 20, disodium hydrogen phosphate, potassium dihydrogen phosphate, potassium chloride, water for injections.

What VidPrevtyn Beta looks like and contents of the pack

- The antigen solution is a colourless, clear liquid.
- The adjuvant emulsion is a whitish to yellowish homogeneous milky liquid.
- Prior to administration, the two components should be mixed. The mixed vaccine is a whitish to yellowish homogeneous milky liquid emulsion.

Each pack contains 10 multidose antigen vials and 10 multidose adjuvant vials.

- Each antigen vial contains 2.5 mL antigen solution in a multidose vial (type 1 glass) with a stopper (chlorobutyl) and an aluminium seal with a green plastic flip-off cap
- Each adjuvant vial contains 2.5 mL adjuvant emulsion in a multidose vial (type 1 glass) with a stopper (chlorobutyl) and an aluminium seal with a yellow plastic flip-off cap.

After mixing the antigen solution with the adjuvant emulsion, the vial contains 10 doses of 0.5 mL.

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The following information is intended for healthcare professionals only:

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Posology

VidPrevtyn Beta is administered intramuscularly as a single dose of 0.5 mL at least 4 months after a previous COVID-19 vaccine. VidPrevtyn Beta may be given once as a booster to adults that have received prior vaccination series with either mRNA or adenoviral vector COVID-19 vaccines.

Storage before mixing

Store in a refrigerator (2°C – 8°C). Do not freeze.
Keep the vials in the outer carton in order to protect from light.

Do not use this vaccine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Handling instructions

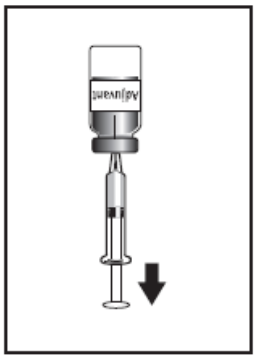
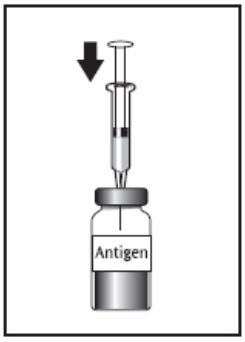
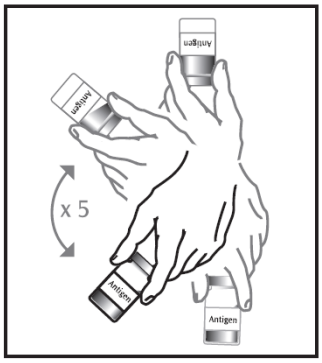
This vaccine should be handled by a healthcare professional using aseptic technique to ensure the sterility of each dose.

VidPrevtyn Beta is supplied as 2 separate vials: an antigen vial and an adjuvant vial.
Prior to administration, the two components must be mixed as per steps below.

Step 1: Place the vials at room temperature (up to 25 °C) for a minimum of 15 minutes before mixing, **protecting them from light.**

Step 2: Invert (without shaking) each vial and inspect them visually for any particulate matter or discolouration. If either of these conditions exist, do not administer the vaccine.

Step 3: After removing the flip-off caps, cleanse both vial stoppers with antiseptic swabs.

Step 4  **Vial 2 of 2**	Using a sterile 21-gauge or narrower needle and a sterile syringe, withdraw the entire contents from the adjuvant vial (yellow cap) into a syringe. Invert the adjuvant vial to facilitate the withdrawal of the full contents.
Step 5  **Vial 1 of 2**	Transfer the full syringe contents into the antigen vial (green cap).
Step 6  **Vial 1 of 2**	Remove the syringe with the needle from the antigen vial. Mix the contents by inverting the vial 5 times. Do not shake. The mixed vaccine is a whitish to yellowish homogeneous milky liquid emulsion.

Step 7: Record the discard date and time (6 hours after mixing) on designated area of vial label.

The volume of the vaccine after mixing is at least 5 mL. It contains 10 doses of 0.5 mL.
An additional overfill is included in each vial to ensure that 10 doses of 0.5 mL can be delivered.

After mixing, administer immediately or store the vaccine at 2°C to 8°C, **protected from light**, and use within 6 hours. After this time period, discard the vaccine.

Preparation of individual doses

Prior to each administration, mix the vial thoroughly by inversion 5 times. Do not shake.
Visually inspect it for any particulate matter and discolouration (see Step 6 for the aspect of the vaccine). If either of these conditions exists, do not administer the vaccine.

Using appropriate syringe and needle, withdraw 0.5 mL from the vial containing the mixed vaccine and administer intramuscularly.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements. Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.