Guidance for management of VidPrevtyn Beta solution and emulsion for emulsion for injection from time of delivery at sites up to the time of administration.

This document is under regular review and updated when relevant new information becomes available. Please check www.immunisation.ie for the current version.

1. Background

VidPrevtyn Beta vaccines are delivered by HSE National Cold Chain Service (NCCS) at a temperature of +2°C to +8°C.

VidPrevtyn Beta vaccines are packed in original boxes of 10 multidose antigen vials (green cap) and 10 multidose adjuvant vials (yellow cap).
The product is packaged in an outer box containing: 10 multidose antigen vials in one smaller box and 10 multidose adjuvant vials in an additional smaller box
i.e. two small boxes contained within one larger box, to form one single product.
The entire product must be stored between +2°C to +8°C.

Antigen and adjuvant vials must be **mixed** before use.
After mixing, each vial contains 10 doses of 0.5ml.

It is indicated as a booster for active immunisation to prevent COVID-19 in **adults (18 years and older)** who have previously received an mRNA or adenoviral vector COVID-19 vaccine i.e. **Booster dose only.** Additional information about the vaccination programme is available in the Clinical Guidance for COVID-19 Vaccination document available at www.immunisation.ie.

SPC is available at https://www.medicines.ie/medicines/vidprevtyn-beta-solution-and-emulsion-for-emulsion-for-injection-35308/spc

2. Responsibilities

The Responsible Person should ensure that VidPrevtyn Beta vaccines are managed as outlined in this Guidance document.

3. Scope

The scope of this document is to provide a set of standardised procedures for the management of VidPrevtyn Beta vaccines at all vaccination sites.

4. Purpose

The purpose of this document is to outline the management of VidPrevtyn Beta vaccines and to provide supporting guidance in relation to:

- Receipt of vaccine
- Vaccine decommissioning
- Shelf-Life
- Storage & Transportation
- Presentation and preparation
- Consumables, Patient Information Leaflet (PIL) & Record Cards and Other Equipment
- Stock Control, Security & Monitoring of Wastage
- Health & Safety

The documents provided may be used as templates to be adapted for local use or may be used as a reference source to check that existing local procedures are robust and comprehensive.

4.1 Receipt of vaccines

- Upon arrival at your site record the maximum, minimum and current temperature of the fridge(s), and reset after recording.
- Prior to receipt of vaccine delivery, ensure the temperature is between +2°C and +8°C.
- Sign for receipt of the vaccines. Vaccines will be at a temperature of +2°C to +8°C when delivered by NCCS.
- Check against the delivery docket
- Immediately place the vaccines (retained in original boxes to protect vials from light) in the fridge.

For additional information please see the following document
https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf

4.2 Vaccine Decommissioning

VidPrevtyn Beta boxes must be decommissioned as per standard procedure, at a site where decommissioning is required. NCCS will decommission for other sites.

4.3 Shelf-Life

4.3.1 Expiry date:

Each component has an expiry date and there are two different expiry dates associated with each outer box:

- One date is printed on the antigen vial label, the antigen carton and the outer box,
- One date is printed on the adjuvant vial label and adjuvant box

The relevant and applicable expiry date is the expiry date on the outer box and antigen vial label and the antigen box.

The expiry date on the outer box and antigen vial label and the antigen box may be the shorter date and this is the only date to be recorded.

4.3.2 DISCARD time

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

DISCARD TIME & DATE must be printed on the Antigen vial once mixed. This is calculated by adding 6 hours to the time of mixing. Discard any unused vaccine after this time period.

From a microbiological point of view, the product should be used immediately. If the vaccine is not used immediately, in-use storage times and conditions are the responsibility of the user

4.4 Storage

Unopened vials of VidPrevtyn Beta should be stored at temperatures between +2°C and +8°C protected from light. Vials should not be re-frozen.

4.5 Presentation and Preparation

VidPrevtyn Beta is packed in original boxes of 10 multidose antigen vials & 10 multidose adjuvant vials. Antigen vial (green cap) & adjuvant vial (yellow cap) must be mixed before use.

After mixing, each vial contains 10 doses of 0.5ml.

Do not pool excess vaccine from multiple vials.

The vaccine should be administered intramuscularly. The preferred site is the deltoid muscle of the upper arm.

Do not administer this vaccine intravascularly, subcutaneously or intradermally.

The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

<u>As per the product SmPC:</u>

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 discoloration. 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: 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, which will be at least 2.5ml.

Step 5: Transfer the full syringe contents into the antigen vial (green cap).

Step 6: 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.

Prior to each administration, mix the vial thoroughly by inversion 5 times. Do not shake. Visually inspect it for any particulate matter and discoloration. 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.

5. Consumables, Patient Information Leaflet (PIL) & Record Cards and Other Equipment

A national distribution service will provide all necessary supplies, to handle, prepare and administer the vaccine including PPE and critical clinical and non-clinical consumables. These are not included in this SOP.

Other Equipment includes:

Anaphylaxis Kits: Refer to National Immunisation Advisory Committee Guidelines https://www.rcpi.ie/healthcare-leadership/niac/immunisation-guidelines-for-ireland. The epinephrine will be provided by a pre-determined community/ hospital pharmacy as agreed by the lead governance organization CHO/HG.

Storage Equipment: A pharmaceutical fridge must be used to store vaccines. The fridge should be set to maintain the temperature at +5°C +/- 3°C, and alarms should take into account the need to maintain the temperature above +2°C and less than +8°C.

Fridges should be validated and monitored in accordance with existing local procedures.

6. Stock Control, Security & Monitoring of Wastage

A physical stock count of COVID-19 vaccine vials should be completed and it should match the stock count recorded on the IT system.

Sites will need to ensure that vaccines are stored securely at all points between receipt and use or disposal.

All waste must be handled in such a way as to prevent theft and /or misuse, both on site and after removal from the site.

Unopened vials (in original cartons) must be returned to NCCS for destruction following the routine protocol for all expired /damaged vaccines.

Dispose empty or partial empty vials into sharps bins safely as per health care management policy. Dispose syringes and needles into sharps bins according to normal local waste management procedures.

Original cartons must have their labels defaced using permanent black marker pens, and placed into appropriate waste sack for incineration, as soon as possible after they become empty.

7. Health & Safety

There are no special handling requirements for routine handling and dealing with VidPrevtyn Beta. Health and Safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.