

# VYJUVEK™ (beremagene geperpavec-svdt) Gel Administration



Healthcare professional (HCP) should apply VYJUVEK gel either at a healthcare professional setting (eg, clinic) or the home setting.



Individuals who are pregnant should not prepare or apply VYJUVEK gel and should avoid direct contact with the treated wounds or dressings from treated wounds



Do not change wound dressing for approximately 24 hours after VYJUVEK gel application

## Supplies

Supplies needed for VYJUVEK gel administration include:

- Two (2) to four (4) administration syringes (based on age of patient)
- Hydrophobic dressing
- Scissors
- Standard dressing
- Protective gloves
- Biohazard waste container
- Virucidal agent for clean-up (eg, 70% isopropyl alcohol, 6% hydrogen peroxide, or <0.4% ammonium chloride)
- Absorbent materials (eg, paper towels)

## Guidelines for Use

Use the VYJUVEK gel in the administration syringes immediately after preparation. If immediate use is not possible, administration syringes containing the VYJUVEK gel:

- Can be stored for **up to 56 hours in the refrigerator** at 2°C to 8°C (35.6°F to 46.4°F)
- Should be kept in the **refrigerator** 2°C to 8°C (35.6°F to 46.4°F) until immediate use

**Discard any used or unused administration syringes in a biohazard waste container.**

## Patient Counseling Information

Advise patients or caregivers of the following precautions prior to and during treatment with VYJUVEK gel:

- Avoid direct contact with treated wounds (eg, touching and scratching) and dressings of treated wounds for approximately 24 hours following VYJUVEK gel application
  - In the event of accidental exposure, instruct patients and exposed individuals to clean the affected area
- Wash hands and wear protective gloves when changing wound dressings
- Disinfect bandages from the first dressing change with a virucidal agent, such as 70% isopropyl alcohol, 6% hydrogen peroxide, or <0.4% ammonium chloride
  - Dispose of the disinfected bandages in a separate sealed plastic bag in household waste
- Dispose of the subsequent used dressings and cleaning materials into a sealed plastic bag and dispose in household waste

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**Vyjuvek™**  
beremagene geperpavec-svdt  
5x10<sup>9</sup> PFU/mL single-use vial

# VYJUVEK™ (beremagene geperpavec-svdt) Gel Administration Steps

In preparation for topically applying VYJUVEK gel to wounds, **wash your hands and put on protective gloves.**

- Follow the steps below for administration of VYJUVEK gel after any wound dressings have been removed and the wound(s) have been properly cleaned

## Step 1: Apply VYJUVEK gel.

Apply VYJUVEK gel to the selected wound(s) in droplets spaced evenly within the wound, approximately 1 cm-by-1 cm apart as illustrated in **Figure 1**.

- The resulting droplet pattern should loosely resemble a grid
- Avoid touching the administration syringe to the skin

## Step 2: Cut and place hydrophobic dressing.

Use the clean scissors to cut the hydrophobic dressing to a size slightly larger than the wound and place the dressing atop the VYJUVEK gel droplets (**see Figure 2**).

## Step 3: Cut and place standard dressing.

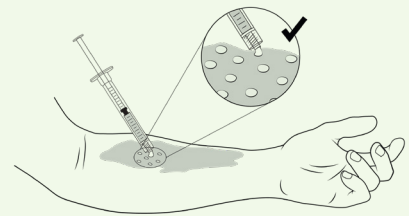
Use the scissors to cut the standard dressing used by the patient to a size slightly larger than the hydrophobic dressing and place the standard dressing atop the hydrophobic dressing as highlighted in **Figure 3**.

## Step 4: Clean and treat all surfaces that have come in contact with VYJUVEK.

Clean all surfaces that may have come in contact with VYJUVEK gel and treat all spills with a virucidal agent such as 70% isopropyl alcohol, 6% hydrogen peroxide, or <0.4% ammonium chloride. Blot using absorbent materials.

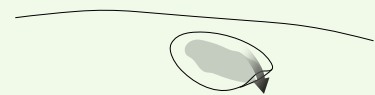
**Figure 1.**

Application of VYJUVEK gel to the wound



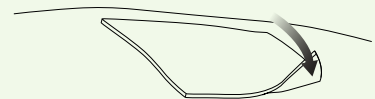
**Figure 2.**

Placing of the hydrophobic dressing over the treated wound



**Figure 3.**

Placing the standard dressing over the hydrophobic dressing



## Disposal of Administration Materials

- Dispose of all materials (eg, used administration syringe(s), absorbent material, protective gloves) that may have come in contact with VYJUVEK gel into a biohazard bag or container
- Discard unused administration syringes containing the VYJUVEK gel after preparation into a biohazard bag or container

**In the event of an accidental exposure to VYJUVEK (eg, through a splash to the eyes or mucous membranes), flush the area with clean water for at least 15 minutes.**

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beremagene geperpavec-svdt  
5x10<sup>9</sup> PFU/mL single-use vial

## INDICATION AND USAGE

VYJUVEK is a topical gel indicated for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the *collagen type VII (COL7A1)* gene.

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

**Accidental Exposure to VYJUVEK gel:** VYJUVEK will not replicate in the subject's cells and does not integrate into the subject cells' native genetic material. For precautions, avoid direct contact with treated wounds (eg, touching or scratching) and dressings of treated wounds for approximately 24 hours following treatment. Wear protective gloves when assisting subjects with changing wound dressings and handling the disposal. In the event of accidental exposure (eg, through a splash to the eyes or mucous membranes), flush with clean water for at least 15 minutes.

Clean all surfaces that may have come in contact with VYJUVEK biological suspension or gel and treat all spills with a virucidal agent, such as 70% isopropyl alcohol, 6% hydrogen peroxide or <0.4% ammonium chloride

Dispose all materials (eg, vial, syringe, needle, cleaning materials) that may have come in contact with VYJUVEK biological suspension or gel into a biohazard bag or container.

### ADVERSE REACTIONS

The most common adverse reactions (>5%) were itching, chills, redness, rash, cough, and runny nose.

**You may report side effects to FDA at 1-800-FDA-1088 or to the Sponsor at 1-844-557-9782**

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