

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

# VYJUVEK<sup>™</sup> Gel Preparation

## Step-by-Step Instructions for VYJUVEK Gel Dose Preparation and Disposal


### 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.

Please see the [Important Safety Information](#) at the end of this document and click here for [Full Prescribing Information](#).

# Overview and Supplies

VYJUVEK™ (beremagene geperpavec-svdt) gel should be prepared at a pharmacy by mixing VYJUVEK biological suspension into the excipient gel. Administration syringes containing the VYJUVEK gel may remain at room temperature (20°C to 25°C [68°F to 77°F]) for **up to 8 hours**. If immediate use is not possible, administration syringes containing the prepared VYJUVEK gel can be stored for **up to 48 hours in the refrigerator** at 2°C to 8°C (35.6°F to 46.4°F).

 Individuals who are pregnant should not prepare or apply VYJUVEK gel.

## Preparation of VYJUVEK gel will take about 35 minutes



**AT LEAST 20 minutes to thaw** the VYJUVEK biological suspension and excipient gel vials

**APPROXIMATELY 15 minutes to:**

- Mix the VYJUVEK biological suspension with the excipient gel to create the VYJUVEK gel
- Prepare the administration syringes
- Properly dispose of all preparation materials

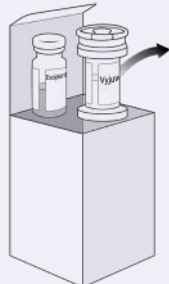
## VYJUVEK Gel Preparation Supplies

- One (1) carton containing (1) VYJUVEK biological suspension vial and (1) excipient gel vial (See [Figure 1](#))
- Two (2) 18-gauge needles
- Two (2) to four (4) 1-mL administration syringes\*
- One (1) 3-mL preparation syringe
- Two (2) to four (4) syringe caps\*
- Protective gloves
- 70% isopropyl alcohol pads
- Biohazard waste container
- Labels for administration syringes
- Virucidal agent—such as 70% isopropyl alcohol, 6% hydrogen peroxide, or <0.4% ammonium chloride—for clean-up
- Absorbent Materials (eg, paper towels)

\*Based on the age of the patient. Six months to <3 years of age (up to 2 syringes each containing 0.4 mL VYJUVEK gel); ≥3 years of age (up to 4 syringes each containing 0.4 mL of VYJUVEK gel).

**Figure 1.**

Carton containing the VYJUVEK biological suspension vial and excipient gel vial



VYJUVEK Shelf-carton



VYJUVEK Biological Suspension Vial



Excipient Gel Vial

### Shelf-cartons may be stored:

- In a freezer at **-15°C to -25°C (5°F to -13°F)**
- In a refrigerator for **up to 1 month** at **2°C to 8°C (35.6°F to 46.4°F)**, if a freezer is not available

VYJUVEK biological suspension is combined with the excipient gel to create VYJUVEK gel.

# Prepare the Preparation Syringe

**Step 1:** Wash your hands and put on protective gloves.

**Step 2:** Thaw the vials.

Remove the VYJUVEK™ (beremagene geperpavec-svdt) biological suspension and excipient gel vials from the shelf-carton and thaw at room temperature (20°C to 25°C [68°F to 77°F]) for **AT LEAST 20 minutes**.

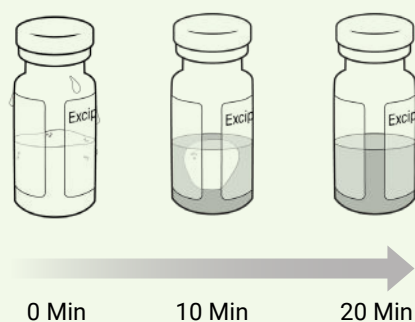
**Visually inspect both vials** to ensure they are in liquid form and completely thawed. **Excipient gel is more viscous and will take longer to thaw** than the VYJUVEK biological suspension.

**Figure 2** shows a timelapse of the thawing of the excipient gel.

Once either the VYJUVEK biological suspension or the excipient gel is thawed, do not refreeze.

**Figure 2.**

Timelapse of excipient gel thaw from 0 minutes to 20 minutes



**Step 3:** Invert the VYJUVEK biological suspension vial 4–5 times.

**DO NOT INVERT** the excipient gel vial.

**Step 4:** Remove caps from vials.

Clean each vial stopper with a fresh 70% isopropyl alcohol pad. Allow them to dry.

**Step 5:** Connect preparation syringe to needle.

Aseptically connect an 18-gauge needle to the 3-mL preparation syringe.

**Step 6:** Remove the needle cap.

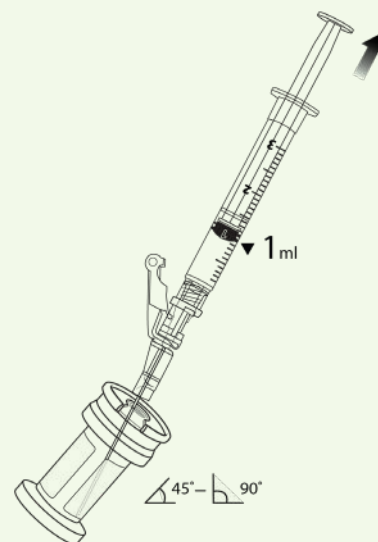
Puncture the VYJUVEK biological suspension vial stopper.

**Step 7:** Withdraw 1 mL of VYJUVEK biological suspension.

Hold the VYJUVEK biological suspension vial at a **45° to 90° angle**, as pictured in **Figure 3**, while pulling the plunger away from the vial.

**Figure 3.**

The removal of 1 mL of VYJUVEK biological suspension using the preparation syringe



Steps 8–15 continue on the next page.

Please click here to access the [Important Safety Information](#) and [Full Prescribing Information](#).

### Step 8: Remove the preparation syringe from the vial.

Preparation syringe (still connected to needle) contains 1 mL of VYJUVEK™ (beremagene geperpavec-svdt) biological suspension from the vial. **DO NOT engage the safety lock.**

### Step 9: Discard the VYJUVEK biological suspension vial in the biohazard waste container.

### Step 10: Puncture the excipient gel stopper.

Transfer 1 mL of VYJUVEK biological suspension into the excipient gel vial, as illustrated in [Figure 4](#).

### Step 11: Remove air.

**Without removing the needle from the excipient gel vial,** lift the bevel of the needle above the liquid, as highlighted in [Figure 5](#).

*Do not remove any liquid.*

Pull the plunger back to the 1 mL mark to remove air, as shown in [Figure 6](#).

### Step 12: Remove the preparation syringe from the excipient gel vial.

Remove the preparation syringe with the 1 mL of air and engage the safety lock.

### Step 13: Discard the preparation syringe and needle into the biohazard waste container.

### Step 14: Cover excipient gel stopper with an alcohol pad.

Place a 70% isopropyl alcohol pad on top of the excipient gel stopper and hold it tightly in place.

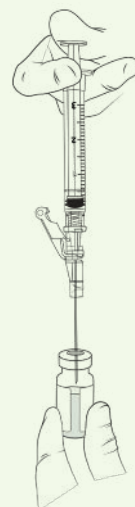
### Step 15: Shake VYJUVEK gel mixture.

Hold excipient gel vial with 70% isopropyl alcohol pad between index finger and thumb, as shown in [Figure 7](#), and **manually shake VIGOROUSLY for 10 seconds.**

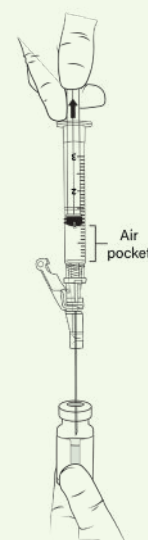
**Figure 4.**  
Transferring VYJUVEK biological suspension to excipient gel vial



**Figure 5.**  
The needle above the liquid without removal of any material



**Figure 6.**  
Pulling the plunger back to the 1 mL mark to remove air



**Figure 7.**  
Manually mixing the excipient gel vial



Mixture of VYJUVEK biological suspension and excipient gel is referred to as VYJUVEK gel.

# Prepare the Administration Syringes

## Step 1: Connect needle to administration syringe.

Aseptically connect an 18-gauge needle to the first 1-mL administration syringe and remove the needle cap.

## Step 2: Insert needle into excipient vial.

Insert the 18-gauge needle into the excipient vial containing VYJUVEK™ (beremagene geperpavec-svdt) gel. [Figure 8](#) shows the inserted needle prior to withdrawal.

## Step 3: Withdraw 0.4 mL of VYJUVEK gel.

Tilt the excipient vial to a 45° to 90° angle as pictured in [Figure 9](#).

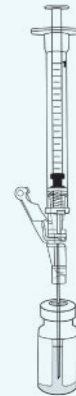
An air pocket may form near the plunger when extracting VYJUVEK gel.

## Step 4: Disconnect administration syringe containing 0.4 mL of mixed VYJUVEK gel.

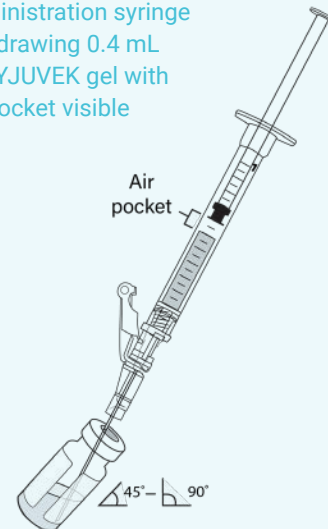
**DO NOT REMOVE THE NEEDLE FROM** the excipient gel vial stopper. Lift the bevel of the needle above the VYJUVEK gel and disconnect the administration syringe, leaving the needle in the excipient gel vial stopper, as illustrated in [Figure 10](#).

*Steps 5–7 continue on the next page.*

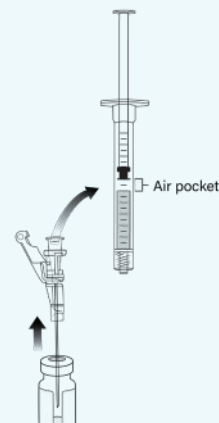
**Figure 8.**  
Needle within  
VYJUVEK gel  
prior to withdraw



**Figure 9.**  
Administration syringe  
withdrawing 0.4 mL  
of VYJUVEK gel with  
air pocket visible



**Figure 10.**  
Disconnecting the  
administration  
syringe containing  
VYJUVEK gel with  
air pocket visible



### Step 5: Remove air pockets from administration syringe.

**DO NOT FLICK** the syringe to remove the air pocket.

Manipulate the plunger up and down, until all air pockets have been removed, as highlighted in [Figure 11](#).

### Step 6: Cap the administration syringe.

Once capped, as shown in [Figure 12](#), put an appropriate label on the administration syringe and set aside.

**Note:** Administration syringes are labeled as #1, #2, #3, and #4.

### Step 7: Connect a new administration syringe to needle remaining in the excipient gel vial containing VYJUVEK™ (beremagene geperpavec-svdt) gel.

Connect with the bevel of the needle **ABOVE** the VYJUVEK gel, as pictured in [Figure 13](#).

Repeat Steps 3–7 until you have prepared the appropriate number of administration syringes based on age of patient.



**Prepare up to 2 syringes**  
if the patient is aged  
6 months to <3 years  
(total volume = 0.8 mL)

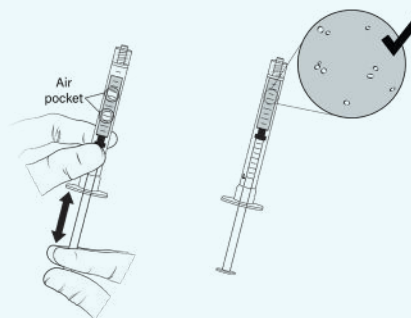


**Prepare up to 4 syringes**  
if the patient is  $\geq 3$  years of  
age (total volume = 1.6 mL)

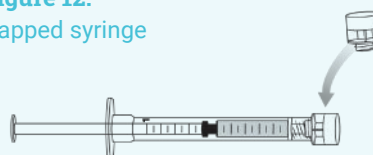
Place the capped administration syringes containing the VYJUVEK gel in a sealable plastic bag. Place the sealable plastic bag with the administration syringes into an appropriate insulated secondary container at 2°C to 8°C (35.6°F to 46.4°F) for transport from the preparation site to the administration site.

VYJUVEK administration syringes may be stored at room temperature (20°C to 25°C [68°F to 77°F]) for up to 8 hours and in the refrigerator (2°C to 8°C [35.6°F to 46.4°F]) for up to 48 hours. Discard administration syringes in a biohazard waste container after these time periods.

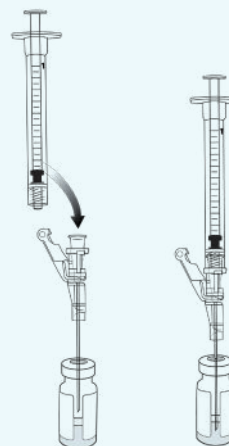
**Figure 11.**  
Manipulation of administration syringe plunger to remove air pockets



**Figure 12.**  
Capped syringe



**Figure 13.**  
Connecting an administration syringe to the needle within the excipient gel vial stopper



# Disposal of Preparation Materials

## Step 1: Dispose of all materials used to prepare administration syringes.

Discard the excipient gel vial (with the needle within the vial stopper) into the biohazard waste container.

## Step 2: Clean all surfaces and treat all VYJUVEK™ (beremagene geperpavec-svdt) spills.

Any surface that may have come in contact with the VYJUVEK biological suspension or gel should be cleaned. Treat all VYJUVEK spills with a virucidal agent such as 70% isopropyl alcohol, 6% hydrogen peroxide, or <0.4% ammonium chloride. Blot using absorbent materials.

## Step 3: Dispose of used absorbent materials and protective gloves.

The used absorbent materials and protective gloves should be discarded in a biohazard waste 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.

## 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.

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.

Please click here for [Full Prescribing Information](#).



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