

INSTRUCTIONS FOR USE

VYJUVEK (vye-JOO-vek) Gel

(beremagene geperpavec-svdt)

biological suspension mixed with excipient gel, for topical use

This Instructions for Use contains information on how to apply VYJUVEK gel.

Read the Instructions for Use before you start using VYJUVEK gel. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

You or your caregiver should be shown how to apply VYJUVEK gel before the first use.



VYJUVEK Gel Syringe

Important Information You Need to Know Before Applying VYJUVEK Gel

Before Starting VYJUVEK Gel

Individuals who are pregnant or nursing should not prepare or apply VYJUVEK gel and should avoid direct contact with the treated wounds or dressings from treated wounds, as this has not been formally studied. It is important to tell your healthcare provider if you are breastfeeding or plan to do so. They will then help you decide whether to stop breast-feeding, or whether to stop taking VYJUVEK gel, taking into account the benefit of breast-feeding to the baby and the benefit of VYJUVEK gel to you.

If you are allergic to beremagene geperpavec-svdt or any of its ingredients, you should not be given VYJUVEK gel.

Tell your healthcare provider about your standard of care routine including medications (prescribed and over the counter), bathing routine, dressing use, etc. before starting VYJUVEK gel.

How is VYJUVEK Gel Supplied?

Syringes containing VYJUVEK gel will be provided by the pharmacy in a sealable plastic bag. VYJUVEK gel in the syringes is ready for administration.

Measures for Accidental Exposure

To avoid accidental exposure follow the below instructions for the administration and handling of VYJUVEK gel:

- Wash hands and wear protective gloves while administering VYJUVEK gel.
- In the event of an accidental exposure through a splash to the eyes or mouth, flush with clean water for at least 15 minutes.
- Avoid direct contact with treated wounds (e.g., touching or scratching) and dressings of treated wounds until the next dressing change.
- Disinfect bandages from the first dressing change with a virucidal agent, such as 70% isopropyl alcohol, 6% hydrogen peroxide, or <0.4% ammonium chloride, and dispose of the disinfected bandages in a separate sealed plastic bag in household waste.

Storing VYJUVEK Gel Syringes

Follow the instructions provided by the pharmacy and do not use the syringes past their expiration.

- VYJUVEK gel syringes are provided by the pharmacy in a refrigerated (2° to 8°C (35.6° to 46.4°F)) container.
- VYJUVEK gel syringes can be stored at room temperature (20 to 25°C (68° to 77°F)) for up to 8 hours prior to application. Administration syringes can be kept in an appropriate insulated or temperature regulated secondary container for up to 48 hours at 2° to 8°C (35.6° to 46.4°F).

- Store VYJUVEK gel syringes out of the reach of children.
- Do NOT heat the syringes or place them in the microwave.

Applying VYJUVEK Gel

Work with your healthcare provider to determine the best wound preparation, administration and dressing routine that works for you.

It may not be possible to treat all wounds each week. VYJUVEK gel should be applied to wounds until they are closed before selecting new wound(s) to treat. Weekly treatment of previously treated wounds should be prioritized if they re-open.

If a dose is missed, VYJUVEK gel should be administered as soon as possible, and weekly treatments will continue. It is not recommended to stop your treatment without first consulting your doctor or nurse.

Wound Preparation

The wounds should be clean before applying VYJUVEK gel.

- Gently remove any medicines, ointments, drainage, scabbing, and dead skin at the wound area.
 - Bathing is not required.
- Leaving wounds uncovered can be painful to some patients. Ensure your area is set-up and ready prior to beginning application.
 - In some cases, it may be best to keep wounds covered and treat one area at a time, removing dressings as you go.
- Do not use products or dressing that may contain anti-viral agents within 24 hours prior to use of VYJUVEK gel.
 - If you are unsure if a product contains an anti-viral agent, refer to the Manufacturer's website at the end of this document for more information or contact your healthcare provider on what to avoid.

Supplies

Below is the list of supplies needed for VYJUVEK gel administration:

- VYJUVEK gel syringes
- Hydrophobic dressing
 - Refer to the Manufacturer's website at the end of this document or contact your healthcare provider for more information on hydrophobic dressing options.
- Clean scissors
- Standard dressing
- Gloves
- Biohazard container
- Virucidal agent and absorbent material for clean-up

Follow the steps below for VYJUVEK gel administration.

The administration syringe should be primed prior to the initial application by pulling the plunger down and gently pushing it upwards, so that a small droplet of VYJUVEK gel forms at the tip of the syringe.

Step 1. Apply VYJUVEK gel to the selected wound(s) in droplets spaced evenly within the wound, approximately 1 cm-by-1 cm apart (width of a fingertip). The resulting droplet pattern should loosely resemble a grid. Avoid touching the administration syringe directly to the wound, only the droplet will touch the wound (**Figure 1**).

Note: You can treat the wound underneath the blister cap after it has been drained. Additionally, the VYJUVEK gel can be applied directly to the hydrophobic dressing in the same 1 cm-by-1 cm pattern to the size of the wound, if direct administration is difficult.

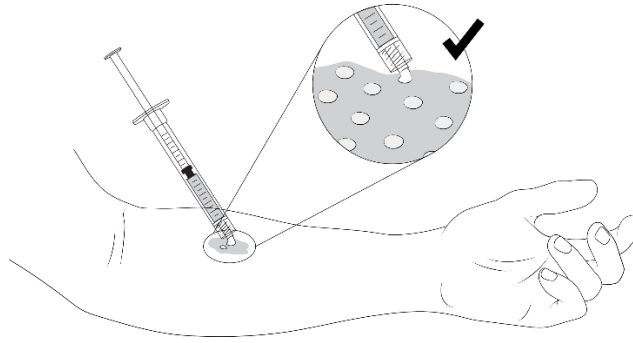


Figure 1 Application of VYJUVEK gel to the wound

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

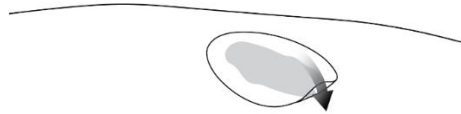


Figure 2 Placing the hydrophobic dressing over the treated wound

Step 3. Use the scissors to cut the standard dressing to a size slightly larger than the hydrophobic dressing and place the standard dressing atop the hydrophobic dressing (**Figure 3**).

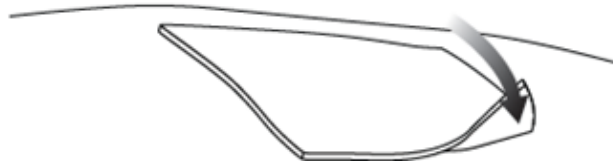


Figure 3 Placing the standard dressing over the hydrophobic dressing

Step 4. The VYJUVEK gel dressing should be left in place until the next dressing change. Disinfect VYJUVEK gel dressings, place in a sealable bag and discard into the household waste. Continue with your standard of care routine.

Disposal and Clean-up of VYJUVEK Gel

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

Dispose all materials (e.g., used and unused syringe (expired), cleaning materials) that may have come in contact with VYJUVEK gel into a biohazard container.

Once the VYJUVEK gel dressings are removed and disinfected with a virucidal agent, place them in a sealable bag and discard into the household waste. Standard of care routine can then be continued.

Additional Information

Manufactured by: Krystal Biotech, Inc.
2100 Wharton Street, Suite 701
Pittsburgh, PA 15203
U.S. License No. 2301

For more information, go to www.vyjuvek.com or call 1-844-5-KRYSTAL (1-844-5-579-7825)

This "Instructions for Use" has been approved by the U.S. Food and Drug Administration.
Approved: September 2025