INSTRUCTIONS FOR USE

FILSUVEZ (fill-sue-vez)

(birch triterpenes)

topical gel

Important information: FILSUVEZ is for use on the skin (topical use) only. Do not use FILSUVEZ in or around your eyes or mucous membranes (for example, the mouth, vagina, or anus).

This Instructions for Use contains information on how to apply FILSUVEZ. Read this Instructions for Use before you start using FILSUVEZ. Ask your healthcare provider if you have any questions.



Important Information You Need to Know Before Applying FILSUVEZ

- Use FILSUVEZ exactly as your healthcare provider tells you to use it.
- Apply FILSUVEZ directly to the wound or to the dressing surface that will be in contact with the wound.
- Clean wounds before applying FILSUVEZ as instructed by your healthcare provider.
- Apply FILSUVEZ with a clean or gloved hand.
- Apply FILSUVEZ at each dressing change until the wound is completely healed.
- **Do not** get FILSUVEZ in or apply around the eyes, or mucous membranes (For example, mouth, vagina, or anus). If you get FILSUVEZ in your eyes or mucous membranes, rinse with clean water right away. Contact your healthcare provider if you have any discomfort.
- Wash hands after applying FILSUVEZ and caring for wounds.
- The tube of FILSUVEZ is for one-time use only. After the tube has been opened, apply the FILSUVEZ gel right away. Throw away any remaining gel and the tube after use.

• Check the expiration date on the FILSUVEZ tube. Do not use FILSUVEZ if the expiration date has passed. Call your pharmacist or healthcare provider for instructions.

Gather your supplies

- a new tube of FILSUVEZ
- gloves (if using)
- · sterile, non-adhesive dressing

Applying FILSUVEZ

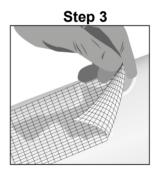
- Wash your hands with soap and water or wear gloves.
- Open a new tube of FILSUVEZ. Apply the gel right away.
- You can apply FILSUVEZ in 2 ways, either directly to the wound **or** to the non-adhesive dressing surface that will be in contact with the wound.

Option 1: Apply FILSUVEZ directly to wound.

 Apply a 1 mm layer of FILSUVEZ to the wound (See Step 1). Cover the entire wound surface with a 1 mm layer of FILSUVEZ (Step 2). **Do not** rub in the gel. Cover the wound with a sterile, non-adhesive wound dressing (see Step 3).







or

Option 2: Apply FILSUVEZ directly to sterile, non-adhesive dressing.

 Apply a generous layer of FILSUVEZ directly to the sterile, non-adhesive dressing (see Step 1). Cover the entire non-adhesive dressing with FILSUVEZ (Step 2). Cover the wound with the dressing so that the gel is in direct contact with the wound (see Step 3). Secure the non-adhesive wound dressing as directed by your healthcare provider.

Step 1



Step 2



Step 3



How should I store FILSUVEZ?

Store FILSUVEZ at room temperature between 68°F to 77°F (20°C to 25°C). Do not freeze.

Keep FILSUVEZ and all medicines out of the reach of children.

How should I throw away (dispose of) FILSUVEZ?

Throw away (dispose of) any remaining FILSUVEZ and the tube right away after use in household trash or through a drug take-back option, if available. Go to www.fda.gov/drugdisposal for more information on drug disposal.

Manufactured by: Lichtenheldt GmbH, Pharmazeutische Fabrik, Werk 1, Industriestr. 7-11, 23812 Wahlstedt, Germany For more information, call 1-855-303-2347 or go to www.filsuvez.com

This Instructions for Use has been approved by the U.S. Food and Drug Administration. Approved: December-2023