



For adult and pediatric patients 6 months of age and older  
with dystrophic or junctional epidermolysis bullosa (EB)

## Getting Started With FILSUVÉZ

This guide will help you better  
understand your treatment.

### Important Safety Information

#### What is FILSUVÉZ (birch triterpenes) topical gel for?

FILSUVÉZ is a prescription medicine used on the skin to treat wounds that may happen with dystrophic and junctional epidermolysis bullosa (EB) in adults and children 6 months of age and older.

It is not known if FILSUVÉZ is safe and effective in children younger than 6 months of age.

Please see **Important Safety Information** throughout.  
Please see full **Product Information** and  
**Patient Information**.



**Filsuvez®**  
(birch triterpenes) topical gel

# What is FILSUVÉZ?



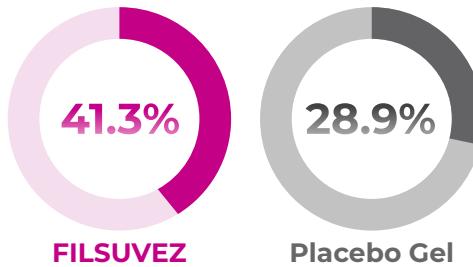
FILSUVÉZ is a prescription medicine used on the skin to support wound healing in adults and children with dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB).

## What should I expect from treatment with FILSUVÉZ?

You should experience wound healing and closure in about **45 days**, as seen in a phase 3 study of FILSUVÉZ conducted in 223 EB patients—195 with DEB and 26 with JEB.

# 45 days

In that same study, **41.3% of people using FILSUVÉZ achieved wound closure in 45 days** compared with 28.9% of those using the placebo gel.



## Important Safety Information (cont'd)

### What is the most important safety information I should know?

**FILSUVÉZ may cause a serious side effect of allergic reactions.** Allergic reactions and skin reactions to FILSUVÉZ may include the following symptoms: red itchy bumps (hives), skin rash, redness or itching. If you get any of these symptoms, stop using FILSUVÉZ right away and call your healthcare provider.

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# How should I apply FILSUVÉZ?



## Step 1



Clean all wounds and apply a generous layer of FILSUVÉZ to each nonadhesive wound dressing or directly to the wounds with a clean or gloved hand. **Do not** rub in the gel.

## Step 2



Spread FILSUVÉZ, ensuring that each layer of gel is about the thickness of a credit card.

## Step 3



Apply dressings to all wounds and reapply FILSUVÉZ with each dressing change until all wounds are fully healed.

**Always use FILSUVÉZ exactly as instructed by your healthcare provider.**



**Watch a demonstration on how FILSUVÉZ is applied.**

Simply scan the QR code or visit [www.filsuvez.com](http://www.filsuvez.com) to learn more.

## Important Safety Information (cont'd)

### What are the possible side effects of FILSUVÉZ?

The most common side effect of FILSUVÉZ is application site reactions, such as pain and itchy skin.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088

**Please see Important Safety Information throughout.**

**Please see full Product Information and**

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# What else should I know about using FILSUEZ?



FILSUEZ should be applied evenly to **all wounds** at **every wound dressing change**. You may use the same tube on **multiple wounds** during a single dressing change.



**One tube of FILSUEZ covers about two 5x4-inch bandages**, nearly the same area as a business-sized envelope. Use the Coverage Calculator found in your Starter Kit to determine how many tubes you need for your wounds at each dressing change, but **do not place this tool directly on your wounds**.



**Each tube of FILSUEZ should only be used once.** Once the tube has been opened, apply the gel to all of your wounds immediately and then dispose of any remaining gel and the tube in your household trash.



**If the tube runs out during a dressing change**, open a new tube and continue applying the gel until all of your wounds are covered.



**FILSUEZ should be stored at 68°F to 77°F (20°C to 25°C).** Do not freeze.



**Do not use FILSUEZ in or around the eyes or mucous membranes** (mouth, vagina, or anus). If accidental contact does occur, immediately wash with clean water and contact your doctor if you have any discomfort.

## Important Safety Information (cont'd)

### How should I take FILSUEZ?

**See the detailed “Instructions for Use” that comes with FILSUEZ for information on how to apply FILSUEZ.**

Use FILSUEZ exactly as your healthcare provider tells you to use it.

**Please see Important Safety Information throughout.**

**Please see full Product Information and**

**Patient Information.**

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# What are the possible side effects of FILSUVÉZ?



## FILSUVÉZ may cause serious side effects

If you get an allergic reaction, stop using FILSUVÉZ immediately and contact your doctor.

- The most common side effect of FILSUVÉZ is application site reactions, such as pain and itchy skin
- If the wounds you are treating with FILSUVÉZ become infected, **stop treatment** and contact your doctor
  - Possible signs of infection include, but are not limited to, the wound becoming red, warm, swollen, painful, and/or draining yellow or greenish fluids (pus)

These are not all the possible side effects of FILSUVÉZ.

Call your doctor for medical advice about side effects.  
You may report side effects to the FDA at 1-800-FDA-1088  
**(1-800-332-1088).**

## Important Safety Information (cont'd)

### How should I take FILSUVÉZ? (cont'd)

The tube of FILSUVÉZ is for one-time use only. After the tube has been opened, apply the gel right away. Throw away any remaining gel and the tube after use.

Please see **Important Safety Information** throughout.

Please see full **Product Information** and

**Patient Information.**

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# What support is available with FILSUVÉZ?

## One-Stop Patient Support

Chiesi Total Care<sup>SM</sup> is a personalized and comprehensive support program designed to help patients using FILSUVÉZ and their healthcare providers.



## The Chiesi Total Care Program Assists With:



### Insurance Consultation and Financial Support

- Help with understanding health insurance benefits and coverage for FILSUVÉZ
- Information on financial assistance options for those who are eligible



### Treatment Support and Logistics Coordination

- Home delivery of your FILSUVÉZ prescription each month
- Help staying on track with prescription refill reminders



### Nurse Support and Personalized Education

- Customized education on EB and how to use FILSUVÉZ available via phone, virtually, or in person with a Registered Nurse



### Dedicated Total Care Team

- A helpful, caring team is here to help, with Pharmacists, Patient Service Coordinators, Reimbursement Support Specialists, and Nursing Support

Call **1-833-670-6464**, Mon-Fri 8am to 8pm ET or visit [www.chiesitotalcare.com](http://www.chiesitotalcare.com) to learn more.

## Important Safety Information (cont'd)

### How should I take FILSUVÉZ? (cont'd)

Do not use around or get FILSUVÉZ in the eyes, or mucous membrane areas, examples are mouth, vagina or anus.

Please see **Important Safety Information** throughout.

Please see full **Product Information** and

**Patient Information.**





**For advocacy information and other related support, please visit:**



**debra of America**, an organization dedicated to helping the EB community since 1980. Learn more at [www.debra.org](http://www.debra.org)



**EB Research Partnership (EBRP)**, a global organization dedicated to funding research to treat and cure EB. Learn more at [www.ebresearch.org](http://www.ebresearch.org)

#### **Important Safety Information (cont'd)**

#### **How should I take FILSUVÉZ? (cont'd)**

If you get FILSUVÉZ in your eyes or mucous membrane area, rinse with clean water right away. Contact your healthcare provider if you have any discomfort.

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## Reimagine Living With EB



FILSUEZ is an FDA-approved topical gel that supports wound healing in people with DEB and JEB.

For more information, visit [www.filsuez.com](http://www.filsuez.com) or simply scan the QR code.

### Important Safety Information (cont'd)

#### How should I take FILSUEZ? (cont'd)

If the wounds you are treating with FILSUEZ become infected, **stop treatment** and contact your healthcare provider. Signs or symptoms of infection may include the wound becoming red, warm, swollen, painful or drains yellow or greenish fluid (pus).

Please see **Important Safety Information** throughout.

Please see full **Product Information** and **Patient Information**.



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