



Dosing and Administration Guide

Visit chiesitotalcare.com
or call 1-833-670-6464
We're ready to help!

Indication and Important Safety Information

Indication

FILSUVEZ is indicated for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in adult and pediatric patients 6 months of age and older.

Warnings & Precautions

Local hypersensitivity and skin reactions have been reported in patients treated with FILSUVEZ, including urticaria and dermatitis. If signs or symptoms of hypersensitivity occur, discontinue use immediately and initiate appropriate therapy.

Please see accompanying full Prescribing Information for FILSUVEZ topical gel.

Filsuvez
(birch triterpenes) topical gel

Starting your patients on FILSUEZ® (birch triterpenes) topical gel

Apply to Every Wound.* At Every Wound Dressing Change.

*FILSUEZ is for junctional and dystrophic EB wounds.

HOW TO APPLY FILSUEZ

- Clean wounds before applying FILSUEZ
- Apply FILSUEZ with a clean or gloved hand

Step 1



Apply a generous layer of FILSUEZ to a sterile nonadhesive wound dressing so that the gel is in direct contact with the wound. FILSUEZ can also be applied directly to the wound.

Step 2



As you spread the layer of FILSUEZ on the dressing, make sure the layer is about the **same thickness as a credit card**.

If you apply FILSUEZ directly to the wound, **do not** rub in the gel.

Step 3



Apply the dressing to the wound.

Reapply FILSUEZ each time your dressing is changed until the wound is completely healed.

A tube of FILSUEZ contains enough gel to cover about two 5x4-inch bandages, **nearly the same area as a business-sized envelope**.

Apply a layer of FILSUEZ about the thickness of a credit card

- FILSUEZ should not be used on full-thickness wounds.
- Patients treated with FILSUEZ have experienced local hypersensitivity, including rash and contact dermatitis. If signs and symptoms of local or systemic hypersensitivity occur, discontinue FILSUEZ immediately and start appropriate therapy.
- If a FILSUEZ-treated wound becomes infected, discontinue treatment to that wound until the infection has resolved.

Indication and Important Safety Information

Adverse Reactions

The most commonly reported adverse reaction in clinical trials was pruritis and pain at the wound application site (7.3%).

Please see accompanying full Prescribing Information for FILSUEZ topical gel.

Easy to use, sterile, single-use tubes

PRESCRIBING NOTES



Available through specialty pharmacy

Across the Phase 3 study population, patients used an average of 27 tubes per month (median 19 tubes)*



SINGLE USE



9.5 in.

4.125 in.

Apply a layer of FILSUEVZ about the thickness of a credit card (1mm)

1 tube covers same area as a business envelope

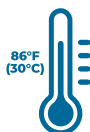
*Data on file, Amryt Pharmaceuticals, Inc.

USING FILSUEVZ



SINGLE USE

The tube of FILSUEVZ should only be used once. Once the tube has been opened, apply the gel to wounds immediately and then **discard the tube and any remaining gel.**



Store FILSUEVZ below 86°F (30°C) and do not freeze.



Do not use FILSUEVZ in or around the eyes or mucous membranes (mouth, vagina, or anus). If accidental contact does occur, patients should be instructed to immediately wash with clean water and contact their doctor if they have any discomfort.



Patients will receive a starter kit with guidance on how to use FILSUEVZ once their prescription has been shipped.

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Patient Counseling Information

Please refer to Prescribing Information for administration instructions.

To report SUSPECTED ADVERSE REACTIONS, contact Chiesi USA Inc. at 1-888-661-9260 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information for FILSUVEZ topical gel.

For more information, visit FILSUVEZ.com/HCP

Chiesi Total CareSM Program offered through PANTHERx Rare Pharmacy.

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