

Package leaflet: Information for the patient

Filsuvez gel birch bark extract

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Filsuvez is and what it is used for
2. What you need to know before you use Filsuvez
3. How to use Filsuvez
4. Possible side effects
5. How to store Filsuvez
6. Contents of the pack and other information

1. What Filsuvez is and what it is used for

Filsuvez gel is a herbal medicinal product which contains dry extract from birch bark.

It is used to treat wounds in adults and children (age 6 months and older) who have a type of the condition “epidermolysis bullosa” (EB) called “dystrophic” (DEB) or “junctional” (JEB). This is a condition where the outer layer of the skin separates from the inner layer, making the skin very fragile and causing wounds to appear.

2. What you need to know before you use Filsuvez

Do not use Filsuvez

- if you are allergic to birch bark or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Filsuvez.

If you get an allergic reaction, **stop using Filsuvez immediately** and see your doctor or nurse. Signs of an allergic reaction include:

- itching, swelling and redness of the skin that is more severe on the area where the medicine has been applied.

Wound infection is a **serious complication** that can occur during the healing process. Possible signs of a wound infection are:

- yellow or greenish fluid (pus) draining from the wound,
- red, warm, swollen, or increasingly painful skin around the wound.

If you have a wound infection, you may need to **stop using Filsuvez** and another treatment may be required. Your doctor or nurse will let you know if treatment with Filsuvez can be restarted once the infection has gone.

People with EB are more likely to develop a type of skin cancer called “squamous cell carcinoma” (SCC). If you are diagnosed with a skin cancer while using Filsuvez you should talk with your doctor or nurse and **stop using Filsuvez** on that part of your skin.

Filsuvez **does not** contain birch pollen, so it may be used by people with a birch pollen allergy.

Avoid getting Filsuvez in your eyes. If this does happen, rinse your eyes well with clean water. Contact your doctor or nurse if any discomfort continues.

Children

Do not give this medicine to children below 6 months.

Other medicines and Filsuvez

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

There is no information on how Filsuvez could react with other medicines applied to the skin, taken by mouth or injected. Do not apply other products to the wound area at the same time as applying Filsuvez. If you need to use more than one product talk to your doctor or nurse.

Pregnancy, breast-feeding and fertility

No studies have been done on the effects of Filsuvez on pregnant women, but since the absorption of this medicine into the body is extremely low, the risk to the unborn baby is negligible. Filsuvez can be used during pregnancy.

It is not known whether Filsuvez passes into human breast milk, but since the absorption of this medicine into the body is extremely low, the risk to the baby is negligible. Filsuvez can be used during breast-feeding, unless the chest area is being treated.

Since the absorption of this medicine into the body is extremely low, it is not expected to affect fertility.

Driving and using machines

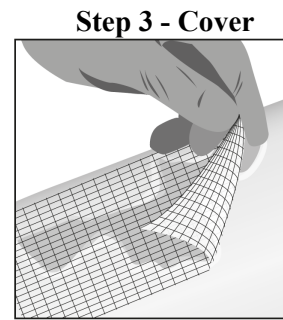
Your ability to drive and use machines will not be affected by this medicine.

3. How to use Filsuvez

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Methods of administration

- **Clean the wound before applying Filsuvez.**
- You can apply Filsuvez in 2 ways:
 1. Apply directly to the wound
 - Apply a thick layer (approximately 1 mm thick) of Filsuvez to the wound (Step 1).
 - Spread plenty of gel and cover the whole area of the wound with a clean or gloved hand (Step 2). **Do not** rub in the gel.
 - Cover with a sterile non-adhesive wound dressing (Step 3).



OR

2. Apply onto a sterile non-adhesive dressing

- Apply a thick layer (approximately 1 mm thick) of Filsuvez to the wound dressing (Step 1).
- Spread plenty of gel on the area that will have direct contact with the wound with a clean or gloved hand (Step 2).
- Cover the wound with the dressing (Step 3).



- Re-apply the gel each time your dressing is changed, until the wound is healed.
- Filsuvez **is not** for internal use. Avoid contact with the eyes, mouth or nostrils. If accidental contact does occur, immediately wash with clean water.
- This tube of sterile gel is for a single application. Once opened, the gel should be used immediately and the tube thrown away, even if there is some gel left. A new tube should be used at each dressing change.

Duration of use

Your doctor, pharmacist or nurse will tell you for how long you should use the gel. If symptoms continue or worsen after use, or if wound complications occur, speak to your doctor, pharmacist or nurse.

If you use more Filsuvez than you should

Filsuvez is applied to the skin and the absorption into the body is extremely low. This makes overdose very unlikely, even if applied to large skin areas and for a long period of time.

If you forget to use Filsuvez

Apply Filsuvez at the next planned change of wound dressing, continuing with your normal routine.

If you stop using Filsuvez

Filsuvez should be used as advised by your doctor, pharmacist or nurse. **Do not stop using it** without consulting your doctor, pharmacist or nurse.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor, pharmacist or nurse straight away if you notice any side effects including those listed below.

Very common (may affect more than 1 in 10 people)

- wound complication (e.g. increase in wound size, wound re-opening, wound pain)

Common (may affect up to 1 in 10 people)

- wound infection
- allergic reaction (hypersensitivity)
- itchy skin
- pain and itching where the medicine is applied
- complications of wound healing

Uncommon (may affect up to 1 in 100 people)

- wound secretion
- skin irritation (dermatitis)
- itchy rash
- purple coloured rash
- pain

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Filsuvez

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and tube after 'EXP'. The expiry date refers to the last day of that month.

Store below 30°C.

This tube of sterile gel is for a single application. Once opened, the gel should be used immediately and the tube thrown away, even if there is some gel left. A new tube should be used at each dressing change.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Filsuvez contains

The active substance is a dry extract from birch bark.

1 g gel contains: 100 mg extract (as a refined dry extract) from *Betula pendula* Roth, *Betula pubescens* Ehrh. as well as hybrids of both species (equivalent to 0.5-1.0 g birch bark), including 84-95 mg triterpenes calculated as the sum of betulin, betulinic acid, erythrodiol, lupeol and oleanolic acid.

Extraction solvent: n-Heptane.

The other ingredient is refined sunflower oil.

What Filsuvez looks like and contents of the pack

Filsuvez is a colourless to slightly yellowish, opalescent non-aqueous gel.

Filsuvez gel is packed in white collapsible aluminium tubes. The tubes are closed with a tamper-evident aluminium membrane and fitted with a white polypropylene screw cap. The tube is packed in a carton.

Pack sizes:

1 and 30 tubes of 9.4 g or

1, 10 and 30 tubes of 23.4 g gel.

Not all pack sizes may be marketed.

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Detailed information on this medicine is available on the Medicines and Healthcare products Regulatory Agency (MHRA) web site: <http://www.mhra.gov.uk>