



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Filsuvez (*birch bark extract*)

An overview of Filsuvez and why it is authorised in the EU

What is Filsuvez and what is it used for?

Filsuvez is a medicine that is used in adults and children aged 6 months or older with epidermolysis bullosa (EB).

EB is an inherited disease of the skin that makes the skin very fragile and causes severe blistering and scarring. Filsuvez is used in two types of EB, dystrophic EB and junctional EB, to treat partial-thickness skin wounds. These are wounds where the upper layers of the skin have been damaged.

EB is rare, and Filsuvez was designated an 'orphan medicine' (a medicine used in rare diseases) on 23 February 2011. Further information on the orphan designation can be found here:

ema.europa.eu/medicines/human/orphan-designations/eu-310845

Filsuvez contains a dry extract from two species of birch bark consisting of naturally occurring substances known as triterpenes, including betulin, betulinic acid, erythrodiol, lupeol and oleanolic acid.

How is Filsuvez used?

Filsuvez is available as a gel that should be applied to the wound surface at a thickness of approximately 1 mm and covered by a wound dressing. The medicine can also be applied directly to the wound dressing. The gel should not be applied sparingly, and should be re-applied with every dressing change until the wound has healed. If symptoms do not improve after use or if wound complications occur, your healthcare professional will assess your condition and consider whether to continue treatment.

For more information about using Filsuvez, see the package leaflet or contact your doctor, nurse or pharmacist.

The medicine can only be obtained with a prescription.

How does Filsuvez work?

The exact way Filsuvez works is not fully understood. It is thought that the active substance in Filsuvez, birch bark extract, may help the cells that make up the outer layer of the skin (keratinocytes) grow and move towards the gap created by the wound, thereby helping wounds to heal.

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What benefits of Filsuvez have been shown in studies?

The effectiveness of Filsuvez at treating partial-thickness wounds was investigated in one main study involving 223 adults and children with EB, including dystrophic and junctional subtypes. Of those who were treated with Filsuvez in combination with wound dressing, 41% showed complete closure of the wound within 45 days, compared with 29% who were using a control gel (a dummy treatment) in combination with wound dressing. No difference from the control gel was noted after 90 days.

What are the risks associated with Filsuvez?

The most common side effects with Filsuvez (which may affect more than 1 in 10 people) are wound complications. Other common side effects include skin reactions at the application site, wound infections, pruritis (itching), and hypersensitivity (allergic) reactions (may occur in more than 1 in 100 people).

For the full list of side effects of Filsuvez, see the package leaflet.

Why is Filsuvez authorised in the EU?

Filsuvez gel was shown to be effective for patients with dystrophic and junctional EB at treating partial-thickness wounds, which can be difficult to heal, leading to pain and a risk of infection, and for which treatment options are limited. Although effects were modest, they were considered clinically meaningful for EB patients with dystrophic and junctional EB and the medicine had an acceptable safety profile, with side effects that were localised and manageable. Therefore, the European Medicines Agency decided that the benefits of Filsuvez are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Filsuvez?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Filsuvez have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Filsuvez are continuously monitored. Suspected side effects reported with Filsuvez are carefully evaluated and any necessary action taken to protect patients.

Other information about Filsuvez

Filsuvez received a marketing authorisation valid throughout the EU on 21 June 2022.

Further information on Filsuvez can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/filsuvez

This overview was last updated in 06-2022.