

NCPE Assessment

Plain English Summary

April 2025

Drug name: Birch bark extract (*pronounced burch bark ex-trac-t*) for treatment of partial-thickness wounds associated with dystrophic and junctional epidermolysis bullosa in patients six months of age and older.

Brand name: Filsuvez[®]

HTA ID: 23069

What is the NCPE?

The National Centre for Pharmacoeconomics (NCPE) is a team of experts who look at the health benefits and costs of medicines. The HSE asks us to advise on whether or not a new medicine is good value for money. We give unbiased advice to help the HSE provide the most effective, safe and cost-effective (value for money) treatments for patients.

How do we make our recommendations?

Our main focus is on the health benefits and cost effectiveness of a medicine. We look at the wider costs and health benefits associated with a new medicine, for example:

- Does the new medicine work better than other treatments available in Ireland?
- Is the new medicine easier to give or easier to take compared with other treatments available in Ireland?
- Does the new medicine reduce the need for patients to be hospitalised?
- Does the new medicine improve the quality of a patient's life over other treatments available in Ireland?
- Will the new medicine save resources elsewhere within the health system?

We review the information from clinical trials along with the cost and value for money data presented by the pharmaceutical company. We ask doctors and other healthcare professionals for advice about any health benefits of the new medicine compared with current treatments. We also ask patient organisations to send us their views on how the new drug may improve patients' day-to-day experience of living with a disease.

What is birch bark extract used for?

Epidermolysis bullosa is a condition that leads to fragile skin that blisters and breaks, particularly in response to minor trauma or friction. Birch bark extract gel (Filsuvez[®]) has anti-inflammatory and wound healing properties and is indicated for the treatment of partial-thickness wounds associated with dystrophic and junctional epidermolysis bullosa in patients six months and older. In addition to enhancing wound healing, birch bark extract has been shown to reduce the requirement for daily dressings which can be painful,

particularly in children thereby impacting on patient's quality of life.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider funding birch bark extract if its cost-effectiveness can be improved. The HSE will consider our recommendation and make the final decision about reimbursement (funding). When making the funding decision, the HSE will also consider the additional [criteria](#) outlined in the Health (Pricing and Supply of Medical Goods) Act 2013.

Why did we make this recommendation?

We recommend that the HSE consider providing this medicine if the HSE can agree a suitable price reduction with the pharmaceutical company. We believe that birch bark extract treatment may add benefit as it enhances wound healing and reduces the requirement for daily dressings in patients with dystrophic and junctional epidermolysis bullosa. However, the price of the medicine is too high compared with other ways to manage this condition, and we believe that the medicine is not value for money.

Next steps

When the HSE receives our recommendation, it will look at all the relevant data about birch bark extract. The HSE makes the final decision on reimbursement.

Where can I get more information?

You can get more information about birch bark extract from the following online options:

- the NCPE Technical Summary Document
- Filuvez[®] European Public Assessment Report (EPAR) – [Summary for the public](#) or
- searching for birch bark extract on our website (www.ncpe.ie);
- searching for birch bark extract on the European Medicines Agency (EMA) website (www.ema.europa.eu).

Please refer to the NCPE website for updated information on the reimbursement status of this medicine.