



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 April 2022
EMA/CHMP/188166/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Filsuvez

birch bark extract

On 22 April 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Filsuvez², intended for the treatment of epidermolysis bullosa (EB). The applicant for this medicinal product is Amryt Pharmaceuticals DAC.

Filsuvez will be available as a gel for cutaneous use. The active substance of Filsuvez is birch bark extract (as dry extract, refined) from *Betula pendula* Roth/*Betula pubescens* Ehrh. (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. It is thought to work by modulating inflammatory mediators and stimulating keratinocyte differentiation and migration, thereby promoting wound healing and closure.

The benefit of Filsuvez is its ability to promote healing of EB partial thickness wounds. The most common side effects are wound complications, application site reactions, wound infections, pruritus and hypersensitivity reactions.

The full indication is:

Treatment of partial thickness wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in patients 6 months and older.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

