swissmedic

Summary report on authorisation dated 28 October 2025

Filsuvez® (active substance: refined dry extract from birch bark)

Authorisation in Switzerland: 25 July 2025

Gel for the treatment of superficial wounds in adults and children aged 6 months and over who have dystrophic and junctional epidermolysis bullosa (EB)

About the medicinal product

Filsuvez contains as its active substance a dry extract from the bark of various species of birch.

Filsuvez is used to treat wounds in patients with two types of epidermolysis bullosa (EB) – dystrophic or junctional. Epidermolysis bullosa is a rare genetic disease that makes the skin extremely sensitive. As a result, it blisters and tears easily. This often leads to chronic wounds that do not heal easily and considerably impair patients' lives.

Since these are rare, life-threatening diseases, the medicine has been authorised as an orphan drug. "Orphan drug" is a designation given to medicinal products for rare diseases.

Filsuvez has been authorised by Swissmedic under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in another country with comparable medicinal product control.

In this case, Swissmedic takes into consideration the results of checks carried out by foreign regulatory agencies, provided certain requirements are fulfilled. These involve checks on the quality, efficacy, and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland. The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

In deciding whether to authorise Filsuvez in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency EMA (EMEA/H/C/005035/0000) and has only conducted a limited scientific review.

Since the assessment was based on the assessment report of a foreign partner authority, the preconditions for a full SwissPAR (Swiss Public Assessment Report) and a resulting Summary report on authorisation are not met. Swissmedic refers to the authorisation of the foreign comparator product.

www.ema.europa.eu

Further information on the medicinal product

At the time of publication of the Summary report on authorisation for Filsuvez, the Information for healthcare professionals and the Patient information (package leaflet) were not yet available. As soon as the medicine becomes available in Switzerland, the Information for healthcare professionals and the Patient information will be made available on the following website: www.swissmedicinfo.ch
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.