

Filsuvez® (birch bark extract gel) Now Available For Prescribing in Scotland for Epidermolysis Bullosa through SMC Ultra-Orphan Pathway Following Final Approval of the Data Collection Plan by Scottish Government

- Filsuvez® (birch bark extract gel) – the first licenced therapy in Europe to treat junctional and dystrophic epidermolysis bullosa (EB) - is now available for prescribing via the Scottish Medicines Consortium's (SMC) ultra orphan medicines pathway for an initial three-year period whilst further safety and efficacy data is collected.

MANCHESTER, UK, 4th November 2024 – Chiesi, the international research-focused biopharmaceutical group, today announced that birch bark extract gel is now available for prescribing as a treatment option for junctional and dystrophic epidermolysis bullosa (EB) in Scotland under the SMC's ultra-orphan medicines framework.^{1,2}

The news comes following approval earlier this year by the SMC and offers a treatment option specifically for partial-thickness wounds associated with junctional and dystrophic forms of EB. The therapy can now be prescribed for eligible patients from 30th October 2024.

The availability of birch bark extract gel in Scotland represents an important milestone towards driving equal access to innovative therapies for rare diseases, with the therapy now available across Great Britain.

*"We are truly delighted that birch bark extract gel is now available for patients 6 months and older living with junctional and dystrophic EB in Scotland; this step is a result of close working between patient organisations, the NHS, the SMC, the Scottish Government and Chiesi. The news is even more meaningful to share as it comes during EB Awareness Week, a week dedicated to increasing awareness of this painful and debilitating genetic skin condition, said **David Garzón Lafuente, Head of Rare Diseases, Chiesi UK&I.** "Birch bark extract gel offers hope to patients who endure daily challenges from this condition, and we are pleased that the SMC recognises the urgent need for approved therapies."*

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About epidermolysis bullosa

Epidermolysis bullosa (EB) is a heterogenous group of rare inherited skin disorders caused by mutations in the genes that encode skin anchoring proteins of the dermo-epidermal junction. It is characterised by very fragile skin that is prone to blistering and erosions due to minor trauma or friction, with the resulting wounds usually extending through multiple layers of the skin surface. As well as the high wound burden, there is impaired wound healing and debilitating symptoms such as pain, pruritis, scarring, deformity, and immobility. There are also several systemic complications (for example anaemia, increased risk of infections, osteoporosis, and squamous cell carcinoma). These all can carry considerable morbidity and increased mortality risk.^{3,4}

About Filsuvez® (birch bark extract gel)

Birch bark extract is a sterile gel for cutaneous application use for the treatment of partial thickness wounds associated with dystrophic and junctional EB in patients six months and older.

Birch bark extract gel is approved by the European Medicines Agency and available across Europe.

The Great Britain Summary of Product Characteristics for birch bark extract gel can be found at www.medicines.org.uk/emc/product/13971/smpc.

About Chiesi Group

Chiesi is a research-oriented international biopharmaceutical group that develops and markets innovative therapeutic solutions in respiratory health, rare diseases, and specialty care. The company's mission is to improve people's quality of life and act responsibly towards both the community and the environment.

By changing its legal status to a Benefit Corporation in Italy, the US, and France, Chiesi's commitment to create shared value for society as a whole is legally binding and central to company-wide decision-making. As a certified B Corp since 2019, we're part of a global community of businesses that meet high standards of social and environmental impact. The company aims to reach Net-Zero greenhouse gases (GHG) emissions by 2035.

With over 85 years of experience, Chiesi is headquartered in Parma (Italy), with 31 affiliates worldwide, and counts more than 7,000 employees. The Group's research and development centre in Parma works alongside 6 other important R&D hubs in France, the US, Canada, China, the UK, and Sweden.

For further information please visit www.chiesi.uk.com.

About Chiesi Global Rare Diseases

Chiesi Global Rare Diseases is a business unit of the Chiesi Group established to deliver innovative therapies and solutions for people affected by rare diseases. As a family business, Chiesi Group strives to create a world where it is common to have a therapy for all diseases and acts as a force for good, for society and the planet. The goal of the Global Rare Diseases unit is to ensure equal access so as many people as possible can experience their most fulfilling life. The unit collaborates with the rare disease community around the globe to bring voice to underserved people in the health care system.

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References

¹ The Scottish Medicines Consortium (SMC). birch bark extract gel (Filsuvez®): initial assessment. Available at: <https://scottishmedicines.org.uk/medicines-advice/birch-bark-extract-filsuvez-uo-pathway-smc2651/>

² The Scottish Medicines Consortium (SMC). Ultra-orphan medicines for extremely rare conditions. Available at: <https://www.scottishmedicines.org.uk/how-we-decide/ultra-orphan-medicines-for-extremely-rare-conditions/>.

³ Has C, Bauer JW, Bodemer C, Bolling MC, Bruckner-Tuderman L, Diem A, et al. Consensus reclassification of inherited epidermolysis bullosa and other disorders with skin fragility. Br J Dermatol. 2020 Oct;183(4):614-627. doi: 10.1111/bjd.18921.

⁴ Amryt Pharmaceuticals DAC. Betula pendula Roth, Betula pubescens Ehrh. (as dry extract, refined) (Filsuvez Gel®) Summary of product characteristics. Electronics Medicines Compendium www.medicines.org.uk.