

Chiesi Global Rare Diseases receives Swissmedic approval for FILSUVEZ® topical gel for the treatment of epidermolysis bullosa

Published On: 2025-08-11 12:00

Parma, Italy and Villars-sur-Glâne SA, Switzerland , 11 August 2025 – Chiesi Global Rare Diseases, a business unit of the Chiesi Group established to deliver innovative solutions for people living with rare diseases, announced today that FILSUVEZ® (Oleogel-S10, dry extract from birch bark) was approved by Swissmedic (the Swiss surveillance authority for medicines and medical devices) on 25 July 2025 for the treatment of superficial wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in patients aged 6 months and older.

This is the first time a medicine has received regulatory approval in Switzerland for the treatment of this condition. The approval is based on the double-blind, controlled phase 3 EASE study involving 223 patients.

EB is a serious hereditary and debilitating skin disease, that causes a person's skin to be so fragile it can be injured just from touch. This rare, chronic, and distressing disorder affects infants, children and adults and is intensely painful; recurrent blistering and chronic wounds can result in intolerable pain with limited mobility. Living with EB entails daily challenges to navigate, including slow-healing wounds at risk of infection and painful dressing changes.

FILSUVEZ® is administered at home, allowing it to be integrated into existing treatment routines. The product is applied directly to the wound or wound dressing each time the dressing is changed.

About epidermolysis bullosa

Epidermolysis bullosa (EB) is a rare genetic disorder characterised by extreme skin fragility and blistering. Severe forms lead to chronic blisters, ulcerations, scarring, joint contractures, oesophageal strictures, a high risk of squamous cell carcinoma, infections and premature death.

About FILSUVEZ® topical gel

FILSUVEZ® (Oleogel-S10, dry extract from birch bark) is approved for patients aged six months and older who are affected by dystrophic or junctional EB. The gel is applied directly to the cleaned wound surface in a layer approximately 1 mm thick and then covered with a sterile, non-adhesive wound dressing. Alternatively, the gel can also be applied to the wound dressing, which is then placed on the wound so that the gel is in direct contact with the wound.

About the EASE study

The EASE Study was a Phase III, double-blind, randomised, vehicle-controlled trial conducted to assess a potential treatment for inherited forms of EB, including dystrophic and junctional subtypes. The subjects were randomised and treated for three months in a double-blind manner with either Oleogel-S10 or a placebo gel consisting of refined sunflower oil, yellow beeswax and carnauba wax. The respective gel was applied in a 1 mm thick layer to all wounds each time the wound dressing was changed, i.e. every one to four days.

A superficial wound with an area of 10 to 50 cm² was selected as the target wound by the investigator at the start of the study. This wound was used to determine the primary efficacy endpoint: the proportion of patients in whom the target wound had completely closed for the first time by day 45. After completion of the double-blind phase of the study, it was continued as an open-label study and all patients were treated with Oleogel-S10.

The primary efficacy endpoint was achieved in 41.3 percent of patients in the verum group and in 28.9 percent of patients in the placebo group. In other words, the probability of complete closure of the target wound was increased by 44% with Oleogel-S10.

Side effects occurred with similar frequency in both comparison groups and were mostly mild to moderate.

Long-term observation of participants in the EASE study showed a significant and sustained reduction of approximately 50% in total wound area in patients treated with Oleogel-S10.

About the 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, France and Colombia, Chiesi's commitment to creating shared value for society as a whole is legally binding and central to company-wide decision-making. As a certified B Corp since 2019, Chiesi is 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 90 years of experience, Chiesi is headquartered in Parma (Italy), with 31 affiliates worldwide, and counts more than 7,500 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.