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Summary report on authorisation dated 16 June 2025

Litfulo® (active substance: ritlecitinib)

Authorisation in Switzerland: 3 February 2025

Hard capsules for the treatment of severe alopecia areata in adolescents 12 years of age and older and adults up to a maximum of 65 years of age

About the medicinal product

Litfulo contains the active substance ritlecitinib and is used for the treatment of severe alopecia areata (circular hair loss).

This condition causes sufferers to lose hair from the scalp and can also affect other parts of the body. Alopecia areata occurs when the immune system attacks the hair follicles, leading to bald patches.

Litfulo is indicated specifically for adults up to a maximum age of 65 years and adolescents 12 years of age and older if at least 50 % of the scalp is affected and systemic treatment (i.e. a treatment that doesn't just act locally, but that affects the whole body) is under consideration.

Mode of action

Alopecia areata causes the immune system to attack the hair follicles, resulting in hair loss. Litfulo is an immunosuppressant, i.e. a medicinal product that reduces the activity of the immune system. It reduces the effect of the enzymes JAK3 and TEC kinases, which play an important role in inflammation, thereby enabling the inflammation to subside and the hair to grow back.

Administration

Litfulo is a prescription-only medicine available as hard capsules at the dosage strength of 50 mg.

The recommended dosage is one capsule daily.

The capsules should be swallowed whole with water without being opened, crushed or chewed. The capsules can be taken with or without food.

Efficacy

The efficacy of Litfulo was investigated in the pivotal AA-I study with 718 alopecia areata patients 12 years of age and older. The patients showed a loss of at least 50 % of their scalp hair.

The total treatment period was 48 weeks, subdivided into a 24-week placebo-controlled phase (in which the participants received Litfulo or placebo (dummy drug)) and a 24-week extension phase (in which treatment was continued with Litfulo).

In the study the patients received Litfulo in different dosages. 50 mg once daily proved to be the most favourable dosage in terms of efficacy and safety. After 24 weeks, 13.4 % of the patients on Litfulo achieved almost complete scalp hair coverage, compared to just 1.5 % in the placebo group. This was measured by the SALT score of ≤10. The SALT score (Severity of Alopecia Tool) is a rating scale that measures the severity of the hair loss in alopecia areata, where a score of 0 represents no hair loss and a score of 100 complete hair loss on the scalp. A score of ≤10 corresponds to a minimum of 90 percent coverage of the scalp with hair.

The effect continued to increase until week 48, underlining the sustained efficacy of Litfulo.

Also in terms of satisfaction with the treatment, patients who received Litfulo reported a much greater improvement than those who were taking the placebo.

Precautions, undesirable effects, & risks

The most common undesirable effects were as follows: diarrhoea (9.2 %), acne (6.2 %), respiratory tract infections (6.2 %), urticaria (hives) (4.6%), rash (3.8 %), folliculitis (inflammation of the hair follicles) (3.1 %) and dizziness (2.3 %).

As a result of the mode of action of Litfulo, the body's own immune system may be inhibited during long-term treatment with this medicinal product. Treatment with Litfulo is therefore associated with a risk of serious infections. If an infection occurs, the treatment should be discontinued until it is under control. There is also an increased risk of cancer (malignancies), blood clots and severe cardiovascular incidents such as heart attack or stroke.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Few treatment options are currently available for people, particularly adolescents, who suffer from severe circular hair loss (alopecia areata). Such conditions can cause severe mental stress. Litfulo, containing the active substance ritlecitinib, offers an innovative treatment option and can promote hair regrowth in the sufferers.

Taking all the risks and precautions into account, and based on the available data, the benefits of Litfulo outweigh the risks. Swissmedic has therefore authorised the medicinal product Litfulo, containing the active substance ritlecitinib, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Litfulo®

Information for patients (package leaflet): Information for patients Litfulo®
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.

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