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Litfulo (*ritlecitinib*)

An overview of Litfulo and why it is authorised in the EU

What is Litfulo and what is it used for?

Litfulo is a medicine used to treat adults and adolescents over 12 years of age with severe alopecia areata, an autoimmune disease (a disease caused by the body's own defence system attacking normal tissue) causing hair loss of the scalp or other parts of the body.

Litfulo contains the active substance ritlecitinib.

How is Litfulo used?

Litfulo can only be obtained with a prescription and treatment must be started and supervised by a doctor experienced in the diagnosis and treatment of alopecia areata.

Litfulo is available as capsules taken by mouth once a day. Treatment should be interrupted or stopped if patients experience serious infections or low blood cell levels. Treatment should be stopped if no improvements are seen after 36 weeks.

For more information about using Litfulo, see the package leaflet or contact your doctor or pharmacist.

How does Litfulo work?

In people with alopecia areata, the immune system attacks the hair follicles and causes hair growth to slow or stop altogether, leading to hair loss. The active substance in Litfulo, ritlecitinib, is an immunosuppressant (a medicine that reduces the activity of the immune system). It works by blocking the action of certain enzymes called JAK3 and TEC kinases, which play an important role in inflammation. By blocking these enzymes, ritlecitinib reduces inflammation, allowing hair regrowth in people with alopecia areata.

What benefits of Litfulo have been shown in studies?

The benefits of Litfulo were investigated in a main study involving 718 adults and adolescents over 12 years of age with severe alopecia areata, 261 of whom were given 50 mg Litfulo or placebo (a dummy treatment). All patients had more than 50% hair loss on the scalp before they started treatment. After 24 weeks of treatment, disease symptoms improved in patients given Litfulo: 13% of them were in near remission, meaning that they had more than 90% hair coverage on their scalp, and 23% had

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more than 80% hair coverage. Such improvements were seen in 1.5% of patients given placebo. After 48 weeks, 31% of patients given Litfulo were in near remission. When asked whether their alopecia had improved, 49% of patients given Litfulo stated that their condition had moderately or greatly improved, compared with 9% of patients given placebo.

What are the risks associated with Litfulo?

For the full list of side effects and restrictions with Litfulo, see the package leaflet.

The most common side effects with Litfulo (which may affect up to 1 in 10 people) include diarrhoea, acne, upper respiratory tract (nose and throat) infections, urticaria (itchy rash), rash, folliculitis (inflammation of hair follicles) and dizziness.

Litfulo must not be used in patients with active serious infections, including tuberculosis, or severe liver problems. The medicine also must not be used in women who are pregnant or breast-feeding.

Why is Litfulo authorised in the EU?

Litfulo was shown to be effective in the treatment of severe alopecia areata in adults and adolescents, and the benefits were maintained over time. Although the side effects of Litfulo are considered manageable, there are uncertainties regarding long-term use due to limited data. Several measures have been put in place to minimise risks associated with Litfulo.

Given the importance of scalp hair regrowth for patients with severe alopecia areata, the European Medicines Agency decided that Litfulo's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Litfulo?

The company that markets Litfulo must provide educational materials to healthcare professionals and patients with information on the safety of the medicine, specifically regarding the risk of infections, cardiovascular conditions (diseases affecting the heart or blood vessels), cancer, neurotoxicity (damage to the nervous system) and toxicity to the unborn baby when exposed during pregnancy.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Litfulo have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Litfulo are continuously monitored. Suspected side effects reported with Litfulo are carefully evaluated and any necessary action taken to protect patients.

Other information about Litfulo

Litfulo received a marketing authorisation valid throughout the EU on 15 September 2023.

Further information on Litfulo can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/litfulo.

This overview was last updated in 09-2023.