



FAQ – LITFULO (Ritlecitnib)

What is LITFULO?

LITFULO (Ritlecitnib) is a selective dual Janus kinase 3 (JAK3) and tyrosine protein (TEC) kinase inhibitor approved by the U.S. Food and Drug Administration (FDA) for adults and adolescents 12 years and older with severe alopecia areata (AA) (1). The FDA approved LITFULO for AA in June 2023.

In clinical trials of LITFULO, severe AA was defined as 50% or greater scalp hair loss (2,3). The FDA approval does not define severe AA by the percentage of scalp hair loss specifically. As such, your physician may consider other factors in determining the severity of your alopecia areata, including the negative impact of the disease on emotional and psychosocial functioning, and eyebrow/ eyelash involvement (3). Discuss with your healthcare provider whether LITFULO (ritlecitnib) is an appropriate treatment option for you.

How does LITFULO work?

Hair loss in alopecia areata involves an immune system attack on hair follicles that disrupts the hair growth cycle, causing hair to fall out (4,5). Signaling molecules called cytokines lead to this attack through pathways that utilize members of the Janus kinase (JAK) family of protein messengers in cells. Small molecules known as JAK inhibitors can block the activity of the immune signaling pathways by binding the proteins that are involved in the attack on hair follicles in AA. LITFULO is a selective dual JAK3/TEC inhibitor (3,6). By blocking the JAK3 signaling, fewer cytokines are made, and less inflammation occurs, allowing hair to regrow (6).

How do you take LITFULO?

LITFULO is a once-daily oral pill that can be taken with or without food (7). The FDA-approved dose is 50 mg per day (1,7).

How effective is LITFULO for alopecia areata?

Three randomized, placebo-controlled clinical trials and one long-term trial evaluated the efficacy and safety of LITFULO in a total of 1628 subjects (12 years of age and older) with severe AA (2,3). Hair regrowth was evaluated after 24 weeks. Overall, a statistically significant percentage of study participants with severe AA who took LITFULO achieved 80% or more scalp coverage compared to placebo after six months (2).

What are the most common side effects of LITFULO in people treated for alopecia areata?

The most common side effects ($\geq 1\%$) reported for LITFULO in clinical trials through 24 weeks of treatment were headache, diarrhea, acne, rash, urticaria, inflamed hair pores (folliculitis), fever, atopic dermatitis (eczema), dizziness, blood creatinine phosphokinase increase, herpes zoster (shingles), red blood cell count decrease, and redness and swelling of the lining of the mouth (stomatitis) (8).

What is a 'boxed warning' and why does LITFULO have one?

Boxed warnings, formerly known as “black box warnings,” are safety-related warnings that are assigned to medications by the FDA in order to ensure that any major risks associated with a drug are brought to the consumer’s attention (9). Boxed warnings typically do not apply to any one individual drug but rather to a class, or group, of drugs.

For LITFULO, and all other drugs that fall under the JAK inhibitors class, the boxed warning includes information about the risk for serious infections, mortality, cancer, cardiovascular events, and clotting (thrombosis) (1). The boxed warning that is used on all JAK inhibitor medications is based on a study of tofacitinib (another JAK inhibitor) in patients with

rheumatoid arthritis who were aged 50 years and older and who also had at least one cardiovascular risk factor (10). These patients were also on methotrexate for their rheumatoid arthritis.

Discuss your personal and family health history, smoking history, as well as medication risks with your healthcare provider in the process of making treatment decisions. LITFULO is not for pregnant or breastfeeding women, or individuals with severe liver or kidney disease.

When will the drug be available to the typical alopecia areata patient?

LITFULO is available now.

Is LITFULO available for use outside of the U.S.?

As of this writing, LITFULO is approved in the European Union, Japan, Canada, and the United Kingdom for the treatment of alopecia areata (11, 13, 14). LITFULO is also approved in China under the trade name Lefenox (12).

How can I get LITFULO?

LITFULO is available by prescription only. Any healthcare provider who can write prescriptions can prescribe LITFULO.

A board-certified dermatologist will know the most about alopecia areata and be able to evaluate treatment effectiveness in hair regrowth personalized to your treatment goals.

How long do I have to take LITFULO?

LITFULO should be taken as your doctor prescribes. LITFULO is a treatment for alopecia areata and not a cure. It helps treat the symptoms of the disease. If you stop taking the medication, the symptoms may return.

New research developments will continue to advance treatment improvements with time. The ALLEGRO-LT Phase 3 clinical trial of LITFULO is continuing and will examine the long-term safety and efficacy in adults with AA with 25% or greater hair loss and adolescents from 12 years of age with 50% or greater hair loss (8).

Can children use LITFULO?

Currently, the FDA has only approved LITFULO for use in adults and adolescents (age 12 and older) with severe alopecia areata.

How much does LITFULO cost? Is LITFULO covered by insurance?

The cost of LITFULO will largely depend on your insurance plan. Individual insurance plans vary on coverage and co-pays. As a result, you may pay a different price than someone else for the same drug, depending on your insurance situation. Pfizer offers assistance through the Pfizer Dermatology Patient Access Program, for more information visit their website <https://www.pfizerdermatologypatientaccess.com/>.

Where can someone find additional information on alopecia areata?

For more information, please contact the National Alopecia Areata Foundation (NAAF) by email at info@naaf.org, or visit NAAF's website at www.naaf.org.

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