



## FAQ – LEQSELVI (deuruxolitinib)

### ***What is Leqselvi?***

Leqselvi (deuruxolitinib) is an oral Janus kinase (JAK) inhibitor approved by the U.S. Food and Drug Administration (FDA) for adults with severe alopecia areata (AA). The FDA approved Leqselvi for alopecia areata in July 2024, and it became commercially available in July 2025. Leqselvi is manufactured by Sun Pharma.

Leqselvi was tested in two large, placebo-controlled Phase 3 clinical trials (1,2) involving more than 1,200 patients with at least 50% scalp hair loss. In one of these trials, about one-third of participants (29.6%) taking 8 mg of Leqselvi twice daily for 24 weeks achieved 80% or more scalp hair regrowth, compared to less than 1% of those taking a placebo.

### ***How does Leqselvi work?***

Leqselvi is a member of a class of drugs called Janus kinase (JAK) inhibitors. JAK inhibitors are immunomodulatory drugs. They target the immune system pathway that is overactive in alopecia areata. Immune cells and hair follicles interact through cellular mechanisms that utilize Janus kinase proteins (or JAKs) to transmit signals in the immune system. By taking a JAK inhibitor, the immune cell attack on the hair follicle is blocked (or *inhibited*), allowing the normal hair growth cycle to continue and hair to regrow.

### ***How do you take Leqselvi?***

Leqselvi is a twice-daily oral pill. The approved dose is 8 mg taken with or without food.

### ***How effective is Leqselvi for alopecia areata?***

After 24 weeks of treatment, about one-third of patients in the phase 3 clinical trials achieved 80% hair regrowth. Approximately 3% of participants saw 80% regrowth in 8 weeks (1,2).

### ***What are the most common side effects of Leqselvi in people treated for alopecia areata?***

The most common side effects (1% or greater) reported for Leqselvi in clinical trials for alopecia areata were headache (12.4%), acne (10%), nasopharyngitis (pain or swelling of the nose or throat) (8.1%), and blood creatine phosphokinase increase (5.3%) (2,4).

### ***What medical tests are recommended before starting Leqselvi?***

Your healthcare provider will order several standard lab tests prior to starting your prescription for a JAK inhibitor. For Leqselvi, your doctor will also order a CYP2C9 genotyping test. The cost for this test will be covered by Sun Pharma. Leqselvi is not recommended for individuals who are poor metabolizers of CYP2C9, an enzyme involved in drug metabolism.

### ***What is a ‘boxed warning’ and why does Leqselvi have one?***

Boxed warnings, formerly known as “black box warnings,” are safety-related warnings that are assigned to medications by the FDA to ensure that any major risks associated with a drug are brought to the consumer’s attention (3). Boxed warnings typically do not apply to any one individual drug but rather to a class, or group, of drugs.

For Leqselvi, and all other drugs in the JAK inhibitors class, the boxed warning includes information about the risk for serious infections, mortality, cancer, cardiovascular events (5), and clotting (thrombosis). The boxed warning 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 or older and had at least one cardiovascular risk factor. 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. Leqselvi 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?***

Leqselvi was approved in the U.S. in July 2024, and it became commercially available in July 2025.

### ***Is Leqselvi available for use outside of the U.S.?***

As of this writing, Leqselvi is not available outside of the U.S.

### ***How can I get Leqselvi?***

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

A board-certified dermatologist will be the most knowledgeable about alopecia areata and capable of evaluating treatment effectiveness in hair regrowth tailored to your specific goals.

Like all FDA-approved JAK inhibitors for alopecia areata, Leqselvi requires your doctor to coordinate with your insurance company to obtain prior authorization for coverage. Once approved, your insurance will have its specialty pharmacy dispense the medication. Learn more about prior authorizations, specialty pharmacies, insurance, and patient assistance programs [here](#).

### ***How long do I have to take Leqselvi?***

Leqselvi should be taken as directed by your doctor. Leqselvi is a treatment for alopecia areata and not a cure. It helps treat the symptoms of the disease. Clinical research on [treatment with JAK](#) inhibitors suggests that if the medication is stopped, most patients will lose the hair regrowth they have achieved.

### ***Can children use Leqselvi?***

Currently, the FDA has only approved Leqselvi for use in adults (age 18 and older) with severe alopecia areata.

### ***How much does Leqselvi cost? Is Leqselvi covered by insurance?***

The cost of Leqselvi 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.

Sun Pharma, the manufacturer of Leqselvi, offers a program called the Leqselvi Support™ program to help patients navigate working with their doctor, insurer, and specialty pharmacy to obtain Leqselvi. To learn more, visit [leqselvi.com](https://leqselvi.com) or call 1-855-327-3007 (8:00 AM-8:00 PM ET, Monday-Friday).

### **Where can I find additional information about Leqselvi?**

Additional information about Leqselvi is available at [Leqselvi.com](https://leqselvi.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](mailto:info@naaf.org), or visit NAAF's website at [www.naaf.org](https://www.naaf.org).

### **References**

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2. Leqselvi prescribing information, Section 14 Clinical Studies, pg. 19. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2024/217900s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217900s000lbl.pdf)
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5. Ytterberg SR, Bhatt DL, Mikuls TR, et al. Cardiovascular and cancer risk with tofacitinib in rheumatoid arthritis. *N Engl J Med*. 2022;386(4):316-326. <https://doi.org/10.1056/NEJMoa2109927>