



## FAQ – OLUMIANT (baricitinib)

### ***What is Olumiant?***

Olumiant (baricitinib) is an oral Janus kinase (JAK) inhibitor approved by the U.S. Food and Drug Administration (FDA) for adults with severe alopecia areata (AA) (1). The FDA approved Olumiant for AA in June 2022.

In clinical trials of baricitinib, severe AA was defined as 50% or greater scalp hair loss (2). The FDA approval does not define severe AA by the percentage of scalp hair lost. 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 Olumiant (baricitinib) is an appropriate treatment option for you.

### ***How does Olumiant work?***

Hair loss in alopecia areata (AA) involves an immune system attack on hair follicles that disrupts the hair growth cycle (4). 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 that are involved in the attack on hair follicles in AA. Olumiant (baricitinib) is a JAK inhibitor (5). By blocking the JAK signaling, fewer cytokines are made, and less inflammation occurs, allowing hair to regrow.

### ***How do you take Olumiant?***

Olumiant is a once-daily oral pill. For most patients the recommended dose is 2 mg per day, but some may be treated with 4 mg daily, including those with more extensive scalp hair loss (5). Olumiant is available as 4 mg and 2 mg tablets, and should be taken exactly as your doctor prescribes.

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

Two Phase 3 clinical trials evaluated the efficacy and safety of Olumiant in 1,200 adults with severe AA (2). Hair regrowth was evaluated in both studies after 36 weeks. Overall, a statistically significant percentage of study participants with severe AA who took Olumiant achieved 80% or more scalp coverage compared to placebo (2).

The clinical trial results showed that in patients taking 2 mg per day of Olumiant, nearly 23% of patients in the first study and 19% of patients in the second study, achieved 80% or more scalp hair coverage. At the 4 mg per day dose, nearly 39% and 36% of patients in the first and second studies respectively, achieved 80% or more scalp hair coverage (2). In addition, 24-26% of patients taking 4mg per day of Olumiant achieved 90% or more hair coverage after 36 weeks of treatment (6).

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

The most common side effects ( $\geq 1\%$ ) reported for Olumiant in clinical trials for alopecia areata were upper respiratory tract infections (cold or sinus infections), headache, acne, increased cholesterol levels (hyperlipidemia), increased muscle enzyme levels, urinary tract infections, increased liver enzyme levels, inflammation of hair follicles (folliculitis), tiredness, lower respiratory tract infections, nausea, genital yeast infection, low red blood cell count (anemia), low white blood cell count (neutropenia), stomach-area (abdominal) pain, shingles (herpes zoster), and weight gain (5,6).

### ***What is a 'boxed warning' and why does Olumiant 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 (7). Boxed warnings typically do not apply to any one individual drug but rather to a class, or group, of drugs.

For Olumiant, 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) (5). 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 (8). 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. Olumiant 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?***

Olumiant is available now. Olumiant was approved in the U.S. in 2018 for the treatment of moderate to severe rheumatoid arthritis and in May 2022, for the treatment of COVID-19 in certain hospitalized adults (9). As of June 2022, Olumiant has been approved at a higher dosage for AA (1).

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

As of this writing, Olumiant is approved in the European Union and in Japan for the treatment of alopecia areata (10, 11).

### ***How can I get Olumiant?***

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

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 Olumiant?***

Olumiant should be taken as your doctor prescribes. Olumiant 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. Clinical trials of Olumiant are continuing and will examine treatment out to 200 weeks (2).

### ***Can children use Olumiant?***

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

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

The cost of Olumiant will largely depend on your insurance plan (12). 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. (12)

Eli Lilly offers a program called Olumiant Together, to help patients navigate working with their doctor, insurer, and specialty pharmacy to obtain Olumiant. To learn more, visit <https://www.olumiant.com/olumiant-together> or call 1-844-658-6426.

### ***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](http://www.naaf.org).

## References

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