



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Olumiant (*baricitinib*)

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

What is Olumiant and what is it used for?

Olumiant is a medicine used for treating:

- adults with moderate to severe rheumatoid arthritis (a disease causing inflammation of the joints) when standard treatment with disease-modifying anti-rheumatic drugs (also known as 'DMARDs') has not worked well enough or if patients cannot tolerate them. Olumiant can be used either alone or in combination with the disease modifying drug methotrexate;
- adults and children from 2 years of age with moderate to severe atopic dermatitis (eczema) when treatments applied to the skin are not sufficient or appropriate;
- adults with severe alopecia areata (a disease causing hair loss of the scalp or other parts of the body);
- children aged 2 years and older with active juvenile idiopathic arthritis (inflammation of the joints in children) in whom DMARDs did not work or cannot be tolerated.

Olumiant contains the active substance baricitinib.

How is Olumiant used?

Olumiant can only be obtained with a prescription and treatment must be started by a doctor who has experience in the diagnosis and treatment of the conditions for which it is used.

Olumiant is available as tablets to be taken by mouth once a day. The tablet may be dissolved in water when given to children who are unable to swallow whole tablets.

Treatment may be temporarily stopped in patients who develop an infection, which is a known side effect of the medicine, or in those with abnormal levels of red blood cells or certain white blood cells.

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

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How does Olumiant work?

The active substance in Olumiant, baricitinib, is an immunosuppressant (a medicine that reduces the activity of the immune system). It works by blocking the action of enzymes known as Janus kinases. These enzymes play an important role in the processes of inflammation and damage that occur in rheumatoid arthritis, atopic dermatitis, alopecia areata and juvenile idiopathic arthritis. By blocking the enzymes, baricitinib reduces joint, skin and hair follicle inflammation and other symptoms of these diseases.

What benefits of Olumiant have been shown in studies?

Rheumatoid arthritis

Three studies in around 2,500 patients with rheumatoid arthritis showed that Olumiant improves symptoms, such as tenderness and joint swelling, in patients whose previous disease-modifying drugs have not worked well enough. In these studies, treatment with Olumiant (alone or with disease-modifying medicines such as methotrexate and adalimumab) resulted in more patients achieving an improvement of 20% or more in a standard symptom score (ACR 20) than treatment with comparator medicines and placebo (a dummy treatment). The results of the three studies after 12 weeks of treatment are as follows:

- in patients previously treated with methotrexate, 70% of patients (339 out of 487) on Olumiant achieved at least a 20% improvement in symptom scores, compared with 61% of patients (202 out of 330) on adalimumab and 40% (196 out of 488 patients) on placebo;
- in patients previously treated with conventional disease-modifying drugs, 62% of patients (140 out of 227) on Olumiant achieved at least a 20% improvement, compared with 40% of patients (90 out of 228) on placebo;
- in patients previously treated with a class of disease-modifying drugs called TNF-inhibitors, 55% of patients (98 out of 177) on Olumiant achieved at least a 20% improvement, compared with 27% of patients (48 out of 176) on placebo.

Olumiant has also been studied in patients who had not received previous treatment. In one study involving 584 patients, Olumiant was more effective than methotrexate. However, long-term safety data are missing and these results alone are therefore not sufficient to support Olumiant use in previously untreated patients.

Atopic dermatitis

Three main studies in around 1,600 adults with atopic dermatitis for whom treatments applied to the skin had not worked well enough or were not suitable showed that Olumiant improved their symptoms. In 2 studies, 14 to 17% of those given Olumiant had skin clear or almost clear of inflammation after treatment for 16 weeks compared with 5% of those given placebo. In a study in which Olumiant or placebo were added to treatment with corticosteroid medicines applied to the skin, this was 31% with Olumiant and 15% with placebo. The benefits in those for whom Olumiant worked appeared to continue with longer-term treatment.

An additional study involved 483 children from 2 years of age with moderate to severe atopic dermatitis for whom treatments applied to the skin had not worked well enough or were not suitable. Results showed that, after 16 weeks of treatment, skin was clear or almost clear of inflammation in 42% of patients given Olumiant, compared with 16% of those given placebo.

Alopecia areata

Two main studies in 1200 adults with severe alopecia areata (experiencing loss of at least 50% of scalp hair) showed that Olumiant was effective at reducing hair loss compared to placebo. In these studies, after 36 weeks of treatment, the extent of hair loss improved from over 50% to under 20% of scalp hair in 34% of the participants taking 4 mg of Olumiant and in 20% of the participants taking 2 mg of Olumiant, compared with 4% of the participants taking placebo.

The benefits of Olumiant appeared to continue with longer-term treatment.

Juvenile idiopathic arthritis

A main study looked at the effect of Olumiant in 220 children and adolescents between 2 and 18 years of age who had juvenile idiopathic arthritis and had an insufficient response to at least one DMARD. In this study, all patients were first given Olumiant for 12 weeks, with 76% (167) of the patients showing an improvement in their symptoms after this period. In the second part of the study, 163 of these patients then either continued taking Olumiant or were given a placebo for up to 32 weeks. When patients continued on Olumiant, they were less likely to have a flare up (a sudden worsening of symptoms); 17% (14 out of 82) of patients on Olumiant had a flare up, compared with 51% (41 out of 81) of those given placebo.

What are the risks associated with Olumiant?

For the complete list of side effects and restrictions with Olumiant, see the package leaflet.

In adults, the most common side effects with Olumiant used alone or in combination, which may affect more than 1 in 10 people, are increased blood cholesterol levels and, nose and throat infections. Common side effects (which may affect up to 1 in 10 people) include headache, herpes simplex infections (cold sores) and urinary tract infections.

In children and adolescents with juvenile idiopathic arthritis, side effects in the main study were consistent with those seen in adults with the exception of headache, which was a very common side effect. Common side effects (which may affect up to 1 in 10 people) included neutropenia (low levels of white blood cells) and pulmonary embolism (an obstruction in a blood vessel in the lung); in the main study these were seen in 1 patient each.

In children and adolescents with atopic dermatitis, side effects were consistent with those seen in adults with the exception of neutropenia, which was a common side effect.

Olumiant must not be used during pregnancy

Olumiant should only be used if no suitable treatment alternatives are available in patients aged 65 years or above, in patients with a history of cardiovascular disease (such as heart attack or stroke) or with risk factors for such a disease (such as current or previous long-term smokers), or in patients at increased risk of cancer.

Why is Olumiant approved?

The European Medicines Agency decided that Olumiant's benefits are greater than its risks and it can be authorised for use in the EU.

The Agency considered that Olumiant was shown to be effective at improving symptoms of rheumatoid arthritis in patients when previous treatment with disease-modifying drugs has not worked well enough or if patients cannot tolerate them. The Agency also took into account the lack of treatment options for these patients, and the fact that Olumiant can be given by mouth, which is convenient for patients.

Similarly, for patients with atopic dermatitis and alopecia areata whose other treatment options are limited, its benefits were clinically relevant, particularly in patients with atopic dermatitis when combined with corticosteroid treatment of the skin. In children and adolescents between 2 and 18 years of age, the medicine was effective at treating juvenile idiopathic arthritis and atopic dermatitis. Overall, its side effects are considered manageable, and several measures have been put in place to minimise the risks with this medicine, particularly infection.

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

The company that markets Olumiant will provide educational materials to healthcare professionals and patients with information about the risks with the medicine, particularly the risk of serious infections, blood clots, major cardiovascular events and cancer in certain patients. They will also include a reminder that Olumiant should not be taken during pregnancy and that women taking Olumiant must use contraception during treatment and for at least one week after stopping treatment.

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

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

Other information about Olumiant

Olumiant received a marketing authorisation valid throughout the EU on 13 February 2017.

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

This overview was last updated in 10-2023.