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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 in adults for treating:

- 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;
- moderate to severe atopic dermatitis (eczema) when treatments applied to the skin are not sufficient or appropriate.

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. It is available as tablets to be taken by mouth. The usual dose is 4 mg once a day, but this can be reduced to 2 mg once a day when the disease is under control. The dose may also need to be reduced in patients who have impaired kidney function, in patients who have an increased risk of infections and in those aged over 75 years or who are taking certain other medicines. For more information about using Olumiant, see the package leaflet or contact your doctor or pharmacist.

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 and atopic dermatitis. By blocking the enzymes, baricitinib reduces joint and skin inflammation and other symptoms of these diseases.

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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, 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 comparator medicines and placebo. 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 patients 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, the figures were 31% with Olumiant and 15% with placebo.

The benefits in those for whom Olumiant worked appeared to continue with longer-term treatment.

What are the risks associated with Olumiant?

The most common side effects with Olumiant used alone or in combination, which may affect more than 1 person in 100, are increased blood cholesterol levels, nose and throat infections, headache and herpes infections (in patients treated for rheumatoid arthritis these were herpes zoster [shingles] infections, in patients with atopic dermatitis they were herpes simplex). For the full list of side effects of Olumiant, see the package leaflet.

Olumiant must not be used during pregnancy. For the full list of restrictions, see the package leaflet.

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 is convenient for patients. In terms of safety, being an oral treatment means that Olumiant does not have the same risks as other DMARDs given by injection such as allergic reactions related to the way the medicine is given. Similarly, for atopic dermatitis patients whose other treatment options are limited, its benefits were clinically relevant, particularly when combined with corticosteroid treatment of the skin. 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 ensure that doctors who are expected to prescribe the medicine receive an information pack on the risks with Olumiant, particularly the risk of infection and blood clots, and the monitoring that should be carried out in patients. Patients will be given a special alert card that summarises the safety information about the medicine.

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 10-2020.