



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EPAR summary for the public

Olumiant

baricitinib

This is a summary of the European public assessment report (EPAR) for Olumiant. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Olumiant.

For practical information about using Olumiant, patients should read the package leaflet or contact their doctor or pharmacist.

What is Olumiant and what is it used for?

Olumiant is a medicine used for treating rheumatoid arthritis (a disease causing inflammation of the joints).

It is used in patients with moderate to severe arthritis 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.

Olumiant contains the active substance baricitinib.

How is Olumiant used?

Treatment with Olumiant must be started by a doctor who has experience in the diagnosis and treatment of rheumatoid arthritis. 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, who have an increased risk of infections and in those aged over 75 years or who are taking certain other medicines. For further information, see the package leaflet.

The medicine can only be obtained with a prescription.

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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 process of inflammation and damage of the joints that occurs in rheumatoid arthritis. By blocking the enzymes, baricitinib reduces the inflammation and other symptoms of the disease.

What benefits of Olumiant have been shown in studies?

Three studies in around 2,500 patients 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.

What are the risks associated with Olumiant?

The most common side effects with Olumiant used alone or in combination with methotrexate were increased blood cholesterol levels, nose and throat infections and nausea (which may affect 2 or more people in 100). Infections reported with Olumiant treatment also included herpes zoster (shingles). For the full list of all side effects reported with 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 Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Olumiant's benefits are greater than its risks and recommended that it be approved for use in the EU.

The CHMP 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 CHMP 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. 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 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.

Other information about Olumiant

The European Commission granted a marketing authorisation valid throughout the European Union for Olumiant on 13. February 2017.

The full EPAR for Olumiant can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find/medicine/Human%20medicines/European%20public%20assessment%20reports). For more information about treatment with Olumiant, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2017