EMA/103898/2017
EMEA/H/C/004214

EPAR summary for the public

Xeljanz

tofacitinib

This is a summary of the European public assessment report (EPAR) for Xeljanz. 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 Xeljanz.

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

What is Xeljanz and what is it used for?

Xeljanz is a medicine for treating adults with moderate to severe rheumatoid arthritis, a disease that causes inflammation of the joints.

Xeljanz is used together with methotrexate after treatment with one or more medicines known as disease-modifying anti-rheumatic drugs (DMARDs) has not worked well enough or has led to troublesome side effects. It can also be taken alone by patients who cannot take or are intolerant to methotrexate.

Xeljanz contains the active substance tofacitinib.

How is Xeljanz used?

Xeljanz is available as a 5-mg tablet to be taken by mouth twice a day. Treatment may be stopped in patients who develop infection, which is a known side effect of the medicine, or in those with abnormal blood tests. The dose may also be lowered in some patients with reduced kidney or liver function. For more information, see the package leaflet.

Xeljanz can only be obtained with a prescription, and treatment should be started and supervised by a specialist doctor experienced in treating rheumatoid arthritis.

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How does Xeljanz work?

The active substance in Xeljanz, tofacitinib, works by blocking the action of enzymes known as Janus kinases. These enzymes play an important role in the process of inflammation and joint damage that occur in rheumatoid arthritis. By blocking their action, tofacitinib helps reduce the inflammation and other symptoms of the disease.

What benefits of Xeljanz have been shown in studies?

Six studies in over 4,200 patients with rheumatoid arthritis have shown that Xeljanz is effective at reducing joint pain and swelling, improving joint movement and slowing down joint damage. Most patients in these studies had tried other treatments before and most took Xeljanz with methotrexate.

In one of the studies, where Xeljanz was taken alone, Xeljanz was more effective than methotrexate at slowing down joint damage and reducing symptoms. In another study, Xeljanz taken alone was more effective than placebo at reducing symptoms, such as pain and swelling.

What are the risks associated with Xeljanz?

The most common side effects with Xeljanz are headache, infection and inflammation of the nose and throat, diarrhoea, nausea (feeling sick) and hypertension (high blood pressure).

The most common serious side effects seen with Xeljanz are serious infections such as pneumonia (infection of the lungs), cellulitis (infection of the deep skin tissue), herpes zoster (shingles), urinary tract infection, diverticulitis (infection affecting the intestines) and appendicitis (infection of the appendix) as well as opportunistic infections that can occur in patients with weakened immune systems.

Xeljanz must not be used in patients with active tuberculosis, serious infections or any opportunistic infection. Xeljanz must also not be used in patients with severely reduced liver function or in pregnant and breastfeeding women.

For the full list of side effects and restrictions, see the package leaflet.

Why is Xeljanz approved?

Several studies have shown that Xeljanz taken with methotrexate is effective at treating rheumatoid arthritis in patients who had previously tried other treatments. Xeljanz is also effective when taken alone.

The most important side effect seen with the medicine is infection and there are specific recommendations to help healthcare professionals reduce this risk. In general, the risks with Xeljanz were similar to those of other medicines of its class.

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Xeljanz's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

The company that markets Xeljanz will provide educational materials to healthcare professionals and patients to increase awareness of the risks with the medicine, particularly the risk of serious infections, and how to manage them.

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

Other information about Xeljanz

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