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Xeljanz *(tofacitinib)*

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

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, and psoriatic arthritis (red, scaly patches on the skin with 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.

In patients with rheumatoid arthritis, Xeljanz can also be taken alone by patients who cannot take or are intolerant to methotrexate.

Xeljanz is also used to treat adults with moderate to severe ulcerative colitis, a disease causing inflammation and ulcers in the lining of the gut, after treatment with other medicines has not worked well, has stopped working or has led to troublesome side effects.

Xeljanz contains the active substance tofacitinib.

How is Xeljanz used?

Xeljanz is available as tablet (5 and 10 mg) to be taken by mouth.

For the treatment of rheumatoid arthritis and psoriatic arthritis, the recommended dose is 5 mg taken twice a day.

For the treatment of ulcerative colitis, the recommended dose is 10 mg twice a day for the first 8 weeks and then 5 mg 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.

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

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

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 that occur in rheumatoid and psoriatic arthritis, and ulcerative colitis. By blocking the enzymes' action, tofacitinib helps reduce the inflammation and other symptoms of these diseases.

What benefits of Xeljanz have been shown in studies?

Rheumatoid arthritis

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 (a dummy treatment) at reducing symptoms, such as pain and swelling.

Psoriatic arthritis

Xeljanz, in combination with methotrexate, was shown to be effective at improving symptoms of psoriatic arthritis in 3 main studies.

The first study compared Xeljanz with adalimumab (an injected medicine for psoriatic arthritis) and placebo in 422 patients. The second study compared Xeljanz with placebo in 395 patients. In both studies patients' disease had not responded satisfactorily to other treatment.

In the first study symptoms improved substantially in 50 and 52% respectively of patients taking Xeljanz and adalimumab for 3 months, compared with 33% of those receiving placebo; patients given Xeljanz or adalimumab also showed a greater improvement in their ability to perform everyday activities. Similarly, in the second study Xeljanz was more effective than placebo at improving symptoms (50% of Xeljanz-treated patients versus 24% of those given placebo) and ability to perform everyday activities.

Ulcerative colitis

Xeljanz was more effective than placebo at reducing the symptoms of ulcerative colitis in three main studies.

In the first study in 614 patients with ulcerative colitis, 18% of patients treated with Xeljanz 10 mg twice a day had mild or no symptoms after 8 weeks of treatment compared with 8% of patients who received placebo. Similarly, in a second study with 547 patients, after 8 weeks of treatment 17% of patients treated with Xeljanz had mild or no symptoms compared with 4% of placebo-treated patients.

In a third study with 593 patients, 34% of patients treated with Xeljanz 5 mg twice a day had mild or no symptoms after a year of treatment compared with 11% of patients receiving placebo. Additionally, more patients treated with Xeljanz were able to reduce their use of corticosteroid medicines.

What are the risks associated with Xeljanz?

The most common side effects with Xeljanz (seen in between 1 and 10 patients in 100) are headache, infection and inflammation of the nose and throat, diarrhoea, nausea (feeling sick), joint pain 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 authorised in the EU?

Several studies have shown that Xeljanz is effective at treating rheumatoid arthritis, psoriatic arthritis and ulcerative colitis in patients who had previously tried other treatments. The fact that Xeljanz is taken by mouth may be an advantage compared with existing medicines taken as an injection under the skin.

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 European Medicines Agency therefore concluded that Xeljanz's benefits are greater than its risks and it can be authorised 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.

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

Other information about Xeljanz

Xeljanz received a marketing authorisation valid throughout the EU on 22 March 2017.

Further information on Xeljanz can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 06-2018.