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Jyseleca (*filgotinib*)

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

What is Jyseleca and what is it used for?

Jyseleca is a medicine for treating adults with:

- moderate to severe rheumatoid arthritis, a disease in which the immune system (the body's natural defences) attacks healthy tissue causing inflammation and pain in joints.

  Jyseleca is used alone or with another medicine, methotrexate, after treatment with one or more disease-modifying anti-rheumatic drugs (DMARDs) has not worked well enough or ha caused unacceptable side effects. DMARDs are medicines, such as methotrexate, that slow down the worsening of the disease.

- moderately to severely active ulcerative colitis, a condition in which the immune system attacks healthy tissue in parts of the intestine, causing periodical inflammation leading to sores and bleeding.

  In this case, Jyseleca is given to patients for whom conventional or biological therapies have not worked well enough, have stopped working or are not tolerated.

Jyseleca contains the active substance filgotinib.

How is Jyseleca used?

Jyseleca can only be obtained with a prescription, and treatment should be started by a doctor experienced in treating rheumatoid arthritis or ulcerative colitis.

Jyseleca is available as tablets to be taken by mouth once a day.

Treatment with Jyseleca is only started if blood tests show that the levels of haemoglobin (the protein in blood that carries oxygen) and certain white blood cells are above a set limit. The doctor may interrupt treatment if the levels drop below the set limit.

Treatment should be discontinued in patients with ulcerative colitis who have not shown an adequate benefit from the treatment in the first 22 weeks.

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

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How does Jyseleca work?

Filgotinib, the active substance in Jyseleca, reduces the activity of the immune system. It does this by blocking the action of enzymes known as Janus kinases (JAKs). These enzymes play an important role in the inflammatory processes that occur in rheumatoid arthritis and ulcerative colitis. By blocking the enzymes' action, filgotinib can help to reduce the symptoms of these diseases.

What benefits of Jyseleca have been shown in studies?

Rheumatoid arthritis

Three studies showed that Jyseleca was effective at improving symptoms by at least 20% in patients with moderate or severe rheumatoid arthritis.

The first study involved 1,755 patients whose condition was not controlled well enough with methotrexate. All patients continued to take methotrexate during the study. Symptoms improved after 12 weeks in 77% of patients taking Jyseleca compared with 71% of patients treated with adalimumab (another rheumatoid arthritis medicine) and 50% of those receiving placebo (a dummy treatment).

The second study involved 448 patients whose condition was not controlled well enough with biological DMARDs (medicines made from living cells). All patients continued to take conventional DMARDs, with around 80% of them taking methotrexate. Symptoms improved after 12 weeks in 66% of patients taking Jyseleca compared with 31% of those receiving placebo.

The third study involved 1,249 patients who had not previously taken methotrexate but were at a high risk of their disease worsening. Symptoms improved after 24 weeks in 81% of patients taking both Jyseleca and methotrexate compared with 78% of those taking Jyseleca alone and 71% of those taking methotrexate alone.

Ulcerative colitis

One study in patients who had or had not been treated with a biological agent before showed that Jyseleca was effective at treating ulcerative colitis.

After 10 weeks of treatment, 26% of the patients who had not used biological agents before and were given Jyseleca experienced mild to no symptoms compared with 15% of patients given a placebo. Of the patients who had previously used biological agents, 11% of those taking Jyseleca had mild to no symptoms compared with 4% of patients who were given a placebo. After 58 weeks, 37% of patients taking Jyseleca had mild to no symptoms, compared with 11% of those given a placebo.

What are the risks associated with Jyseleca?

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

The most common side effects with Jyseleca (which may affect up to 1 in 10 people) are nausea (feeling sick), upper respiratory tract infection (nose and throat infection), urinary tract infection, dizziness and lymphopenia (low levels of lymphocytes, a type of white blood cells).

Jyseleca must not be used in patients with active tuberculosis or other serious infections. It must also not be used during pregnancy or breast-feeding. Women who are able to have children must use contraception during treatment with Jyseleca and for at least one week after stopping treatment.

Jyseleca 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 Jyseleca authorised in the EU?

Studies have shown that Jyseleca alone or in combination with methotrexate is effective for treating moderate to severe rheumatoid arthritis when previous treatment with DMARDs had not worked well enough. They have also shown that it is effective for treating adults with moderately to severely active ulcerative colitis for whom conventional or biological treatments did not work or are not tolerated.

In general, the side effects of Jyseleca were similar to those of other medicines of its class, and the most important side effect is infection. Specific warnings and information material are available to help manage these risks.

The European Medicines Agency decided that Jyseleca'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 Jyseleca?

The company that markets Jyseleca will provide educational materials to healthcare professionals and patients (patient alert card) about the risks with the medicine, particularly the risk of serious infections, blood clots, major cardiovascular events and malignancies in certain patients. They will also include a reminder that Jyseleca should not be taken during pregnancy and that women taking Jyseleca 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 Jyseleca have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Jyseleca

Jyseleca received a marketing authorisation valid throughout the EU on 24 September 2020.

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

This overview was last updated in 04-2023.