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Kevzara (*sarilumab*)

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

What is Kevzara and what is it used for?

Kevzara is a medicine for treating:

- adults with moderate to severe rheumatoid arthritis (a disease that causes inflammation of the joints) in whom 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 is used with methotrexate (a DMARD) but can also be used alone if the patient cannot take methotrexate;
- adults with polymyalgia rheumatica (an inflammatory disease that causes muscle pain and stiffness, especially in the shoulders and hips). It is used when corticosteroids are not working well enough or when the disease returned after reducing the corticosteroid dose;
- children 2 years of age and older with active polyarticular juvenile idiopathic arthritis (a disease causing inflammation in the joints that starts in childhood) in whom DMARD treatment has not worked well enough. It is used alone or with methotrexate.

Kevzara contains the active substance sarilumab.

How is Kevzara used?

Kevzara can only be obtained with a prescription. Treatment should be started and supervised by a doctor experienced in diagnosing and treating the conditions for which the medicine is intended.

Kevzara is given as an injection under the skin, once every 2 weeks. In children the injection is given by a healthcare professional, and the dose depends on the child's body weight. For adults, it is available in pre-filled pens and pre-filled syringes, which can be used by the adult or their caregiver if considered appropriate by the healthcare professional and following proper training.

Treatment should be interrupted in patients who develop serious infections until the infection is under control. The dose may have to be lowered in patients with abnormal blood tests.

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

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How does Kevzara work?

The active substance in Kevzara, sarilumab, is a monoclonal antibody (a type of protein) which has been designed to attach to and block the receptor (target) for a molecule called interleukin-6. Interleukin-6 is involved in causing inflammation and is found at high levels in the joints of patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and polymyalgia rheumatica. By preventing interleukin-6 from attaching to its receptor, sarilumab reduces inflammation and other symptoms associated with these conditions.

What benefits of Kevzara have been shown in studies?

Rheumatoid arthritis

Three studies involving over 2,100 adults with rheumatoid arthritis showed that Kevzara is effective at reducing joint pain and swelling, improving joint movement and slowing down joint damage after 24 weeks of treatment.

The first study involved about 1,200 patients whose condition had not responded adequately to treatment with methotrexate; patients received Kevzara plus methotrexate or placebo (a dummy treatment) plus methotrexate. 58% of patients given Kevzara 150 mg and 66% of patients given Kevzara 200 mg had a reduction in symptoms of 20% or more, based on a standard rating score (ACR 20). This compared with 33% of the patients receiving placebo.

A second study involved 546 patients whose condition had not responded adequately to, or who could not take, a TNF-α inhibitor (another type of medicine for rheumatoid arthritis); all patients received Kevzara or placebo in combination with a DMARD. 56% of patients treated with Kevzara 150 mg and 61% of those treated with 200 mg had a reduction in symptoms of 20% or more, compared with 34% of patients on placebo.

A third study involving 369 patients compared Kevzara with adalimumab (another monoclonal antibody for the treatment of rheumatoid arthritis). Patients treated with Kevzara had greater improvement in the function of their joints, compared with patients treated with adalimumab (based on a standard rating score called DAS28-ESR).

Polymyalgia rheumatica

In a main study involving 118 adults aged 50 years and over with polymyalgia rheumatica, patients were given Kevzara or placebo for 52 weeks and their dose of corticosteroids was lowered; 28% of patients given Kevzara achieved sustained remission, meaning that they experienced no signs or symptoms of the disease after 12 weeks of treatment and had no flare ups, had continued low levels of C-reactive protein (a protein that indicates inflammation in the body) and no longer needed extra corticosteroids to control their disease during the study. For patients given placebo, this was 10%. Overall, patients given Kevzara used 777 milligrams of corticosteroids on average during the study, compared with 2,044 milligrams in patients given placebo.

Polyarticular juvenile idiopathic arthritis

A main study involving 101 children aged 2 to 17 with active polyarticular juvenile idiopathic arthritis found that, at doses based on the children's body weight, Kevzara reaches similar blood levels to those seen in adults when the medicine is used to treat rheumatoid arthritis.

Additional supportive data from these children, in whom DMARD treatment had not worked well enough, showed that around 77% of patients responded to treatment with Kevzara after 12 weeks

(based on a standard juvenile idiopathic arthritis scale called JIA ACR70). After 48 weeks, 88% of patients had responded to Kevzara treatment. The study did not compare Kevzara with another medicine or placebo (a dummy treatment).

What are the risks associated with Kevzara?

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

In adults, the most common side effects with Kevzara (which may affect more than 1 in 10 people) include neutropenia (low levels of neutrophils, a type of white blood cell that fights infection). Increased blood levels of a liver enzyme called ALT (a sign of liver problems), reddening of the skin at the site of injection, upper respiratory tract infection (nose and throat infections), and urinary tract infections may affect up to 1 in 10 people.

In children, the most common side effects with Kevzara (which may affect more than 1 in 10 children) include nasopharyngitis (inflammation of the nose and throat), neutropenia and upper respiratory tract infection. Increased blood levels of ALT and reddening of the skin at the site of injection may affect up to 1 in 10 children.

Kevzara must not be used in patients with active, severe infections.

Why is Kevzara approved?

The European Medicines Agency decided that Kevzara's benefits are greater than its risks and that it can be authorised for use in the EU.

Kevzara was shown to be of benefit to patients with moderate to severe rheumatoid arthritis whose condition did not improve adequately or who were intolerant to one or more DMARD medicines and in patients with polymyalgia rheumatica. The benefits seen in people with severe rheumatoid arthritis include reduced symptoms, improved physical function, and slower progression of joint damage. The benefits in people with polymyalgia rheumatica were the sustained reduction in signs and symptoms of the disease and the reduced use of corticosteroid medicines to control their disease.

The cause of inflammation in polyarticular juvenile idiopathic arthritis is believed to be similar to that in rheumatoid arthritis in adults. In children with polyarticular juvenile idiopathic arthritis, Kevzara has been shown to reach comparable levels in the blood to those seen in adults when the medicine is used to treat rheumatoid arthritis. In addition, although the study only included a small number of children with active polyarticular juvenile idiopathic arthritis, Kevzara appears to improve disease symptoms in these children.

The safety profile of Kevzara was considered acceptable and in line with that of other similar medicines. Most side effects were mild to moderate in severity, and the more severe side effects were considered manageable with dose reduction or treatment interruption.

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

The company that markets Kevzara will provide a card for patients, highlighting the risk of serious infections, neutropenia and intestinal perforation (a hole that develops in the wall of the gut) and listing the symptoms for which patients should seek immediate medical attention.

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

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

Other information about Kevzara

Kevzara received a marketing authorisation valid throughout the EU on 23 June 2017.

Further information on Kevzara can be found on the Agency's website: www.ema.europa.eu/en/medicines/human/EPAR/kevzara

This summary was last updated in 12-2024.