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**EPAR summary for the public**

# Kevzara

sarilumab

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

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

## 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.

Kevzara is used when 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.

Kevzara contains the active substance sarilumab.

## How is Kevzara used?

Kevzara is available as a solution for injection in pre-filled pens and pre-filled syringes (150 mg and 200 mg). The recommended dose is 200 mg given as an injection under the skin, once every 2 weeks.

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, see the package leaflet.

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

## 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. By preventing interleukin-6 from attaching to its receptors, sarilumab reduces inflammation and other symptoms associated with rheumatoid arthritis.

## What benefits of Kevzara have been shown in studies?

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 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).

## What are the risks associated with Kevzara?

The most common side effect with Kevzara (which may affect more than 1 in 10 people) is 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, nose and throat infections, and infections of the structures that carry urine (such as the bladder) are also common side effects which may affect up to 1 in 10 people.

Kevzara must not be used in patients with active, severe infections including infections localised to one area of the body. For the full list of side effects and restrictions, see the package leaflet.

## Why is Kevzara approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Kevzara's benefits are greater than its risks and recommended that it be approved 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. The

benefits seen in studies include reduced symptoms, improved physical function, and slower progression of joint damage.

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 an alert 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.

## Other information about Kevzara

The European Commission granted a marketing authorisation valid throughout the European Union for Kevzara on 23 June 2017.

The full EPAR for Kevzara 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 Kevzara, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in June-2017.