Kineret (anakinra)
An overview of Kineret and why it is authorised in the EU

What is Kineret and what is it used for?
Kineret is a medicine that is used to treat:

- signs and symptoms of rheumatoid arthritis (an immune system disease causing inflammation of the joints) in adults. It is used in combination with methotrexate (a medicine used to reduce inflammation) in patients who have not responded adequately to methotrexate alone;
- cryopyrin-associated periodic syndromes (CAPS). CAPS are a group of diseases where patients have a defect in the gene that produces a protein called cryopyrin. This leads to inflammation in many parts of the body, with symptoms such as fever, rash, joint pain and tiredness. Severe disabilities such as deafness and loss of vision may also occur;
- Still’s disease, a disease causing inflammation of joints as well as rash and fever.

For CAPS and Still’s disease, Kineret is used in patients from 8 months of age and weighing at least 10 kg.

Kineret contains the active substance anakinra.

How is Kineret used?
Kineret can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience in the treatment of rheumatoid arthritis, CAPS or Still’s disease as appropriate.

Kineret is available as a solution for injection under the skin. The recommended dose of Kineret for rheumatoid arthritis is 100 mg once a day, given at around the same time each day. For CAPS and Still’s disease, the dose depends on body weight and for CAPS, on the severity of the condition. The injection site should be varied with each dose to avoid discomfort. Kineret should be used with caution in patients who have severely reduced liver function or moderately reduced kidney function.
patients with severely reduced kidney function the doctor should consider giving Kineret every other day

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

How does Kineret work?

The active substance in Kineret, anakinra, is an immunosuppressive medicine (a medicine that reduces the activity of the immune system). It blocks the receptors for a chemical messenger in the body called interleukin 1. This messenger is produced in high levels in patients with rheumatoid arthritis, causing inflammation of the joints and joint damage, and is also involved in the inflammation associated with CAPS and Still’s disease. By attaching to the receptors that interleukin 1 would normally attach itself to, anakinra blocks the activity of interleukin 1, helping to relieve the symptoms of these diseases.

The active substance in Kineret, anakinra, is a copy of a natural human protein called ‘human interleukin 1 receptor antagonist’.

What benefits of Kineret have been shown in studies?

Kineret has been studied in three main studies involving a total of 1,388 patients with rheumatoid arthritis. All three studies compared the effectiveness of Kineret with that of placebo (a dummy treatment). The first study included 468 patients, some of whom had taken other medicines for their disease in the past, and who were given either Kineret on its own or placebo. Results showed that certain doses of Kineret were more effective than placebo in reducing the symptoms of the disease, measured by the doctor and the patient using the ‘American College of Rheumatology’ score, which includes measurements of the number of painful or tender joints, disease activity, pain, disability and levels of C reactive protein in the blood (a marker of inflammation). However, because of the way the study was designed, the results were considered insufficient to support the use of the medicine on its own.

In the other two studies, Kineret was used as an add-on to existing treatment including methotrexate: one study, which involved 419 patients, used a range of doses of Kineret that depended on the patient’s weight, and the other study, which involved 501 patients, used Kineret at a fixed dose of 100 mg once a day. Results showed that Kineret was more effective than placebo when used as an add-on to methotrexate. In the study using a fixed dose of Kineret, 38% of the patients adding Kineret had at least a 20% reduction in symptoms after six months, compared with 22% of those adding placebo.

For CAPS, Kineret has been studied in one main study involving 43 patients with neonatal-onset multisystem inflammatory disease (NOMID/CINCA syndrome, the most severe form of CAPS). Patients were given Kineret at a starting dose of 1 to 2 mg per kg body-weight daily, increased after a month if necessary. Results showed a significant and rapid improvement in symptoms, with a fall in average symptom score from 4.5 to 0.8 within 3 days of starting treatment. The improvement was maintained over a follow-up period of up to 60 months. In addition levels of amyloid A, a marker of inflammation were also reduced.

For Still’s disease, three small studies have been carried out. In the first study, 11 of 15 children with Still’s disease (73 %) had at least a 30% reduction in symptoms after three months treatment with Kineret. A second study in 24 children showed similar results: 67 % had at least a 30% reduction in symptoms after one month compared with 8 % given placebo. The third study was carried out in 22
adult patients who also received corticosteroids for their disease. Patients either received Kineret or another type of medicine, called a DMARD. After one month of treatment, more patients on Kineret (6 out of 12 patients) achieved remission compared with treatment with DMARD (3 out of 10 patients).

**What are the risks associated with Kineret?**

The most common side effects with Kineret (which may affect more than 1 patient in 10) are headache, injection site reactions (redness, bruising, pain and inflammation), and increase in blood cholesterol. For the full list of side effects of Kineret, see the package leaflet.

Kineret must not be used in people who are hypersensitive (allergic) to anakinra, to any of the other ingredients, or to proteins produced by *Escherichia coli* (a type of bacterium). Kineret must not be started in patients who have neutropenia (low levels neutrophils, a type of blood cell that fights infection).

**Why is Kineret authorised in the EU?**

The European Medicines Agency decided that Kineret’s benefits are greater than its risks for the treatment of the signs and symptoms of rheumatoid arthritis in combination with methotrexate, in patients with an inadequate response to methotrexate alone. The Agency recommended that Kineret be given marketing authorisation. Given the beneficial effect and the fact that there were no new safety concerns, the Agency also considered that the benefits outweighed the risks in patients with CAPS and Still’s disease. Although patients with Still’s disease had a higher risk of liver problems, this risk was considered to be outweighed by the medicine’s benefits.

**What measures are being taken to ensure the safe use of Kineret?**

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

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

**Other information about Kineret**

Kineret received a marketing authorisation valid throughout the European Union on 8 March 2002.

Further information on Kineret can be found on the Agency’s website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](https://ema.europa.eu/Find medicine/Human medicines/European public assessment reports).

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