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**EPAR summary for the public**

# Ilaris

canakinumab

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

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

## What is Ilaris and what is it used for?

Ilaris is a medicine for treating the following inflammatory conditions:

- 4 types of periodic fever syndromes (diseases marked by recurring inflammation and fever) in adults and children aged 2 and above:
  - cryopyrin-associated periodic syndromes (CAPS);
  - tumour necrosis factor receptor associated periodic syndrome (TRAPS);
  - hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD);
  - familial mediterranean fever (FMF);
- Still's disease, a rare disease causing inflammation of joints as well as rash and fever (in adults and children aged 2 and above);
- Gouty arthritis, painful inflammation of the joints caused by deposit of urate crystals (in adults).

Ilaris contains the active substance canakinumab.

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## How is Ilaris used?

Ilaris is given as a single injection under the skin every 8 weeks for CAPs and every 4 weeks for the other periodic fever syndromes (TRAPS, HIDS/MKD and FMF) and Still's disease. In patients with gouty arthritis, a single injection is given on-demand to treat gouty arthritis attacks.

Injections are usually given in the upper thigh, upper arm, abdomen or buttocks. After proper training, patients or their caregivers may inject Ilaris themselves if the doctor deems it appropriate (for gouty arthritis the medicine should always be given by a healthcare professional). For information on doses and dose adjustments, see the summary of product characteristics (also part of the EPAR).

Ilaris can only be obtained with a prescription.

## How does Ilaris work?

The active substance in Ilaris, canakinumab, is a monoclonal antibody, a type of protein that has been designed to recognise and attach to a messenger molecule or 'cytokine' in the body called interleukin-1 beta. This messenger is involved in causing inflammation and is found in high levels in patients with periodic fever syndromes, Still's disease and gouty arthritis. By attaching to interleukin-1 beta, canakinumab blocks its activity, helping to reduce inflammation thereby relieving the symptoms of the diseases.

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

### Periodic fever syndromes

Three studies involving 220 adults and children 2 years and older showed that Illaris was effective at reducing relapses of CAPS symptoms after a 24-week treatment period. In one of the studies, none of the patients with CAPS who received Ilaris during the 24-week treatment period had a relapse, compared with 81% of patients who received placebo (a dummy treatment). In the two other CAPS studies, which did not compare Ilaris with any other treatment, 85% of patients on Ilaris had no relapses at all. The proportion of patients with no relapse was lower (around 57%) for children aged 2 to 4 years.

A fourth study in 181 patients with other periodic fever syndromes found that Ilaris was more effective than placebo in achieving a response (symptoms resolved with no new flare ups). The response rates with Ilaris and placebo were 46% and 8%, respectively in patients with TRAPS, 35% and 6% in patients with HIDS/MKD, and 61% and 6% in patients with FMF.

### Still's disease

A study in 84 patients with childhood Still's disease (also known as systemic juvenile idiopathic arthritis, SJIA) found that Ilaris was more effective than placebo at reducing symptoms of arthritis: around 84% of patients who received Ilaris achieved the required reduction in symptoms, compared with about 10% of patients who received placebo. In a second study in childhood Still's disease (177 patients), the risk of experiencing a disease flare was reduced by 64% with Ilaris, compared with placebo. Ilaris treatment also allowed patients to reduce the amount of steroids they take to control inflammation.

Because of the similarities between childhood Still's disease and the adult form (adult-onset Still's disease, AOSD), Ilaris is expected to have similar benefits in adults.

**Gouty arthritis**

Two studies involving 454 patients with gouty arthritis showed that Ilaris was more effective than another anti-inflammatory medicine triamcinolone acetonide at reducing pain. In patients taking Ilaris, after 3 days, the pain level was reduced from 74 to 25 (on a standard rating scale from 0 to 100), whereas in patients taking the comparator the pain level was reduced from 74 to 35. The risk of developing a new gouty arthritis attack was also reduced with Ilaris (17% with Ilaris versus 37% with triamcinolone acetonide).

## What are the risks associated with Ilaris?

Serious infections have been observed in patients taking Ilaris. The most common infections were of the nose and throat. Some infections were unusual or opportunistic infections due to reduced white blood cell levels. For the full list of all side effects reported with Ilaris, see the package leaflet.

Ilaris must not be used in patients with active or severe infection. For the full list of restrictions, see the package leaflet.

## Why is Ilaris approved?

Studies have shown that Ilaris is effective at reducing symptoms or relapses in patients with periodic fever syndromes, Still's disease and gouty arthritis. The main risk with this medicine is infection, mostly affecting the nose and throat. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits seen with Ilaris outweigh its risks and recommended that it be authorised in the EU.

Ilaris was originally authorised under 'exceptional circumstances', because, for scientific reasons, limited information was available at the time of approval. As the company had supplied the additional information requested, the 'exceptional circumstances' ended on 22 March 2017

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

The company that markets Ilaris will provide doctors who will use Ilaris with educational material containing the prescribing information, the patient reminder card and information for doctors containing important safety information about Ilaris, including precautions to be taken when using the medicine.

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

## Other information about Ilaris

The European Commission granted a marketing authorisation valid throughout the European Union for Ilaris on 23 October 2009.

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

This summary was last updated in 03-2017.