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EPAR summary for the public

Rilonacept Regeneron[1]

rilonacept

This document is a summary of the European public assessment report (EPAR) for Rilonacept Regeneron. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Rilonacept Regeneron.

What is Rilonacept Regeneron?

Rilonacept Regeneron is a powder and solvent that are made up into a solution for injection. It contains the active substance rilonacept (80 mg/ml).

What is Rilonacept Regeneron used for?

Rilonacept Regeneron is used to treat 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.

Rilonacept Regeneron is used to treat CAPS that are causing severe symptoms in adults and children aged 12 years and older, including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS).

Because the number of patients with CAPS is low, the diseases are considered 'rare', and Rilonacept Regeneron was designated an 'orphan medicine' (a medicine used in rare diseases) on 10 July 2007.

The medicine can only be obtained with a prescription.

[1] Previously known as Arcalyst.

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How is Rilonacept Regeneron used?

Treatment with Rilonacept Regeneron should be started and supervised by a specialist doctor experienced in diagnosing and treating CAPS.

Rilonacept Regeneron is given as injections under the skin. Adults should be given a starting dose of two injections of 160 mg each in two different parts of the body on the same day. A week later, the patient should start receiving once weekly injections of 160 mg. For children aged from 12 to 17 years, the dose will depend on the patient's weight. The starting dose is 4.4 mg per kilogram body weight (up to a maximum of 320 mg), which is followed a week later by once weekly injections of 2.2 mg/kg (up to a maximum of 160 mg).

Patients may inject themselves once they have been trained if their doctor believes it is appropriate. Patients treated with Rilonacept Regeneron must be given an alert card that summarises the key safety information about the medicine.

How does Rilonacept Regeneron work?

The active substance in Rilonacept Regeneron, rilonacept, is an interleukin inhibitor. It works by attaching to chemical messengers in the body called interleukin-1beta and interleukin-1 alpha. One of these messengers, interleukin-1 beta, is produced at high levels in patients with CAPS, causing inflammation. By attaching to interleukin-1 beta, it blocks its activity, helping to relieve the symptoms of the disease.

How has Rilonacept Regeneron been studied?

In the first part of one main study involving 47 patients with CAPS, patients were given either Rilonacept Regeneron or placebo (a dummy treatment) for six weeks. In the second part of the study, all patients were given Rilonacept Regeneron treatment before receiving either Rilonacept Regeneron or placebo for another nine weeks.

The main measure of effectiveness was how much their symptoms reduced after the six-week treatment and how much the improvements were maintained after the nine-week treatment. Five symptoms (rash, fever or chills, joint pain, tiredness and eye redness or pain) were assessed by patients themselves on a scale from 0 to 10 points.

What benefit has Rilonacept Regeneron shown during the studies?

Rilonacept Regeneron was more effective than placebo at treating symptoms of CAPS. After the six-week treatment, patients who received Rilonacept Regeneron had a reduction in symptoms of 2.5 points on the scale compared with 0.3 points in patients who received placebo. In the second part of the study, symptoms increased more in patients switched to placebo (0.9 points) compared with patients who remained on Rilonacept Regeneron (0.1 points).

What is the risk associated with Rilonacept Regeneron?

The most common side effects with Rilonacept Regeneron (seen in more than 1 patient in 10) are reactions at the injection site, upper respiratory tract infections (colds), sinusitis (inflammation of the sinuses) and headache. For the full list of all side effects reported with Rilonacept Regeneron, see the package leaflet.

Rilonacept Regeneron should not be used in people who may be hypersensitive (allergic) to rilonacept or any of the other ingredients. It must not be used in patients with an active, severe infection.

Blocking interleukin-1 may interfere with the body's immune response to infection and there have been reports of serious infections in patients taking Rilonacept Regeneron.

Why has Rilonacept Regeneron been approved?

The CHMP decided that Rilonacept Regeneron's benefits are greater than its risks and recommended that it be given marketing authorisation.

Rilonacept Regeneron has been authorised under 'exceptional circumstances'. This means that because the diseases are rare, it has not been possible to obtain complete information about Rilonacept Regeneron. Every year, the European Medicines Agency will review any new information that may become available and this summary will be updated as necessary.

What information is still awaited for Rilonacept Regeneron?

The company that makes Rilonacept Regeneron will provide regular information on the safety and effectiveness of Rilonacept Regeneron in adults and children from a registry and will perform a study in children to further investigate what happens to the medicine in the body.

What measures are being taken to ensure the safe use of Rilonacept Regeneron?

The company that makes Rilonacept Regeneron will provide doctors in all Member States who will use Rilonacept Regeneron with a pack containing the prescribing information, a patient alert card and information for doctors explaining the risk of side effects and how to use the medicine properly.

Other information about Rilonacept Regeneron:

The European Commission granted a marketing authorisation valid throughout the European Union for Arcalyst to Regeneron UK Limited on 23 October 2009. The name of the medicine was changed to Rilonacept Regeneron on 23 July 2010. The marketing authorisation is valid for five years, after which it can be renewed.

The summary of opinion of the Committee for Orphan Medicinal Products for Rilonacept Regeneron is available here.

The full EPAR for Rilonacept Regeneron can be found on the Agency's website under EMA website/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Rilonacept Regeneron, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2010.