EMA/407240/2013
EMEA/H/C/002576

EPAR summary for the public

Remsima

infliximab

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

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

What is Remsima and what is it used for?

Remsima is an anti-inflammatory medicine that contains the active substance infliximab. It is usually used when other medicines or treatments have failed, in adults with the following diseases:

- rheumatoid arthritis (an immune-system disease causing inflammation of the joints). Remsima is used with methotrexate (a medicine that acts on the immune system);
- Crohn's disease (a disease causing inflammation of the digestive tract), when the disease is moderate to severe or fistulising (with the formation of fistulae, abnormal passageways between the gut and other organs);
- ulcerative colitis (a disease causing inflammation and ulcers in the lining of the gut);
- ankylosing spondylitis (a disease causing inflammation and pain in the joints of the spine);
- psoriatic arthritis (a disease causing red, scaly patches on the skin and inflammation of the joints);
- psoriasis (a disease causing red, scaly patches on the skin).

Remsima is also used in patients aged between six and 17 years with severe, active Crohn's disease or severely active ulcerative colitis, when they have not responded to or cannot take other medicines or treatments.

See the summary of product characteristics (also part of the EPAR) for full details.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

‘Remsima is a ‘biosimilar’ medicine. This means that Remsima is similar to a biological medicine (the ‘reference medicine’) that is already authorised in the European Union (EU) and that Remsima and the reference medicine contain the same active substance. The reference medicine for Remsima is Remicade. For more information on biosimilar medicines, see the question-and-answer document here.

How is Remsima used?

Remsima is available as a powder to be made up into a solution for infusion (drip) into a vein. It can only be obtained with a prescription and treatment should be started and supervised by a specialised doctor who has experience in the diagnosis and treatment of the diseases that Remsima can be used to treat.

Remsima is usually given as 3 mg per kilogram body weight in rheumatoid arthritis, although the dose can be increased if necessary. The dose is 5 mg per kilogram for the other diseases. How often the treatment is repeated depends on which disease is being treated, and on the patient’s response to the medicine.

Remsima is given as an infusion lasting one or two hours. All patients are monitored for any reactions during the infusion and for at least one to two hours afterwards. To reduce the risk of infusion-related reactions, patients may be given other medicines before or during treatment with Remsima or the infusion time may be slowed down. For more information, see the package leaflet.

Patients who receive Remsima must be given a special alert card that summarises the safety information about the medicine.

How does Remsima work?

The active substance in Remsima, infliximab, is a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (called an antigen) in the body. Infliximab has been designed to attach to a chemical messenger in the body called tumour necrosis factor-alpha (TNF-alpha). This messenger is involved in causing inflammation and is found at high levels in patients with the diseases that Remsima is used to treat. By blocking TNF-alpha, infliximab improves the inflammation and other symptoms of the diseases.

Remsima is produced by a method known as ‘recombinant DNA technology’. The infliximab is made by cells that have received a gene (DNA), which makes them able to produce it.

What benefits of Remsima have been shown in studies?

Remsima was studied to show that it is comparable to the reference medicine, Remicade. Remsima was compared with Remicade in one main study involving 606 adults with rheumatoid arthritis. Patients received either Remsima or Remicade in addition to methotrexate for 30 weeks. The main measure of effectiveness was the change in symptoms. After 30 weeks of treatment Remsima was as effective as Remicade, with around 60% of patients responding to treatment with either medicine.

An additional study was also carried involving 250 patients with ankylosing spondylitis out to show that Remsima produces levels of the active substance in the body that are comparable to the reference medicine, Remicade.

What are the risks associated with Remsima?

The most common side effects with Remsima (seen in more than 1 patient in 10) are viral infections (such as flu or cold sores), headache, upper respiratory-tract infection (colds), sinusitis (inflammation

of the sinuses), nausea (feeling sick), abdominal pain (stomach ache), infusion-related reactions and pain. Some side effects, including infections, may be more common in children than in adults. For the full list of all side effects reported with Remsima, see the package leaflet.

Remsima must not be used in patients who have experienced hypersensitivity (allergy) to infliximab in the past, or who are hypersensitive (allergic) to mouse proteins or any of the other ingredients of Remsima. Remsima must not be used in patients with tuberculosis, other severe infections, or moderate or severe heart failure (an inability of the heart to pump enough blood around the body).

Why is Remsima approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that, in accordance with EU requirements, Remsima has been shown to have a comparable quality, safety and efficacy profile to Remicade. Therefore, the CHMP's view was that, as for Remicade, the benefit outweighs the identified risks. The Committee recommended that Remsima be approved for use in the EU.

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

A risk management plan has been developed to ensure that Remsima is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Remsima, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Remsima will provide educational material to doctors who are expected to prescribe the medicine in adults and children, including information on the safety of the medicine and an alert card to be given to patients. The company will also carry out studies to confirm the long-term safety of the medicine.

Other information about Remsima

The European Commission granted a marketing authorisation valid throughout the European Union for Remsima on 10 September 2013.

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

This summary was last updated in 09/2013.