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Remsima (*infliximab*)

An overview of Remsima and why it is authorised in the EU

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 immune-system diseases:

- rheumatoid arthritis (a disease causing inflammation of the joints). Remsima is used with methotrexate (another 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 fistulas, 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 6 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.

Remsima is a 'biosimilar' medicine. This means that Remsima is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Remsima is Remicade. For more information on biosimilar medicines, see here.

How is Remsima used?

Remsima 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.

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Remsima is available as a powder to be made up into a solution for infusion (drip) into a vein. For treatment of rheumatoid arthritis, Remsima is also available as a solution for injection under the skin in a pre-filled syringe or pen.

Remsima is given as an infusion into a vein 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 may be slowed down. How often the treatment is repeated depends on which disease is being treated, and on the patient's response to the medicine.

For rheumatoid arthritis, after two treatments with infliximab have been given by infusion, Remsima can be given by injection under the skin for subsequent treatments. Patients can inject Remsima themselves once they have been trained.

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

How does Remsima work?

The active substance in Remsima, infliximab, is a monoclonal 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.

What benefits of Remsima have been shown in studies?

Laboratory studies comparing Remsima with Remicade have shown that the active substance in Remsima is highly similar to that in Remicade in terms of structure, purity and biological activity. In addition, Remsima and Remicade given by infusion into a vein were compared 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.

A study was also carried out in 250 patients with ankylosing spondylitis to show that Remsima given by infusion into a vein produces levels of the active substance in the body that are comparable to the reference medicine, Remicade.

Because Remsima is a biosimilar medicine, the studies on effectiveness and safety of infliximab carried out with Remicade do not all need to be repeated for Remsima.

Remsima injection to be given under the skin was shown to be as effective as Remsima given by infusion into a vein in a study involving 343 patients with rheumatoid arthritis. Patients received Remsima by infusion twice, two weeks apart and subsequent treatments were given either by infusion or injection under the skin. After 22 weeks, the reduction of symptoms was comparable for treatment given by infusion into a vein and by injection under the skin.

What are the risks associated with Remsima?

The safety of Remsima has been evaluated, and on the basis of all the studies carried out, the side effects of the medicine are considered to be comparable to those of the reference medicine Remicade.

The most common side effects with Remsima (which may affect more than 1 in 10 people) are viral infections (such as flu or cold sores), headache, upper respiratory-tract infection (nose and throat infections), 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 of 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 authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Remsima has a highly similar structure, purity and biological activity to Remicade and is distributed in the body in the same way. In addition, studies in rheumatoid arthritis and ankylosing spondylitis have shown that the safety and effectiveness of Remsima are equivalent to those of Remicade in the conditions.

All these data were considered sufficient to conclude that Remsima will behave in the same way as Remicade in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Remicade, the benefits of Remsima outweigh the identified risks and it can be authorised for use in the EU.

Remsima given by injection under the skin for rheumatoid arthritis is as effective as Remsima given by infusion and the safety profile is acceptable. It also allows patients the convenience of having their treatment at home.

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

The company that markets Remsima will provide a card to patients that includes information about the medicine and can be used to record tests they have taken.

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

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

Other information about Remsima

Remsima received a marketing authorisation valid throughout the EU on 10 September 2013.

Further information on Remsima can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/remsima.

This overview was last updated in 11/2019.