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# Remicade (*infliximab*)

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

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

Remicade is an anti-inflammatory medicine. 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). Remicade 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).

Remicade 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.

Remicade contains the active substance infliximab.

## How is Remicade used?

Remicade is available as a powder that is made up into a solution for infusion (drip into a vein). Remicade can only be obtained with a prescription and must be given under the supervision and monitoring of a specialised doctor who has experience in the diagnosis and treatment of the diseases that Remicade can be used to treat.

Remicade 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.

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Remicade 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 Remicade or the infusion time may be slowed down. For more information about using Remicade, see the package leaflet or contact your doctor or pharmacist.

## How does Remicade work?

The active substance in Remicade, 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 Remicade is used to treat. By blocking TNF-alpha, infliximab improves the inflammation and other symptoms of the diseases.

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

### Rheumatoid arthritis

Remicade has been studied in a total of 1,432 patients with rheumatoid arthritis in two studies. In these studies, more patients taking Remicade in combination with methotrexate showed a reduction in symptoms than those taking methotrexate alone, as well as less damage to the joints and greater improvements in physical function.

### Crohn's disease

In Crohn's disease in adults, Remicade was compared with placebo (a dummy treatment) in 1,090 adults in four studies. In these studies Remicade produced a greater improvement in symptoms, led to fistulae healing in more patients and increased the time that patients continued to respond to treatment.

The effects of adding Remicade to existing treatment have also been studied in 103 children and adolescents with Crohn's disease who were aged between 6 and 17 years. Most of the patients showed a reduction in symptoms after adding Remicade to their existing treatment.

A sixth study in 508 adult patients looked at the number of patients whose symptoms improved and who did not need additional treatment with corticosteroids (other medicines used in Crohn's disease). The patients were treated for 6 months with Remicade, another medicine azathioprine, or the combination of Remicade and azathioprine. Remicade alone and in combination with azathioprine was more effective than azathioprine alone.

### Ulcerative colitis, ankylosing spondylitis and psoriatic arthritis

For ulcerative colitis (728 adults), ankylosing spondylitis (70 adults) and psoriatic arthritis (104 adults), Remicade has been compared with placebo. More adult patients receiving Remicade had a reduction in symptoms than those receiving placebo.

In a study with 60 children aged between 6 and 17 years with ulcerative colitis 73% of patients responded to treatment with Remicade at week eight (44 out of 60).

### Psoriasis

In a study in 627 adults with psoriasis, Remicade led to a greater improvement in symptoms than placebo.

## What are the risks associated with Remicade?

The most common side effects with Remicade (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 side effects of Remicade, see the package leaflet.

Remicade 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 Remicade. Remicade 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 Remicade authorised in the EU?

The European Medicines Agency decided that Remicade's benefits are greater than its risks and it can be authorised for use in the EU.

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

Patients who receive Remicade must be given a special reminder card. The card will include safety information about the medicine and a record of the dates and results of specific tests that the patient has had so these can be shared with any treating doctor.

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

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

## Other information about Remicade

Remicade received a marketing authorisation valid throughout the EU on 13 August 1999.

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

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