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EPAR summary for the public

Leflunomide medac

leflunomide

This document is a summary of the European public assessment report (EPAR) for Leflunomide medac. 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 Leflunomide medac.

What is Leflunomide medac?

Leflunomide medac is a medicine that contains the active substance leflunomide. It is available as tablets (10, 15 and 20 mg).

Leflunomide medac is a 'generic medicine'. This means that Leflunomide medac is similar to a 'reference medicine' already authorised in the European Union (EU) called Arava. For more information on generic medicines, see the question-and-answer document here.

What is Leflunomide medac used for?

Leflunomide medac is used to treat adults with active rheumatoid arthritis (an immune system disease causing inflammation of the joints) or active psoriatic arthritis (a disease causing red, scaly patches on the skin and inflammation of the joints).

The medicine can only be obtained with a prescription.

How is Leflunomide medac used?

Leflunomide medac treatment should be started and supervised by a specialist who has experience in the treatment of rheumatoid arthritis and psoriatic arthritis. The doctor should carry out blood tests to check the patient's liver, white blood cell counts and platelet counts before prescribing Leflunomide medac, and regularly during treatment.

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Leflunomide medac treatment usually starts with a 'loading dose' of 100 mg once a day for three days, followed by a maintenance dose. The recommended maintenance dose is 10 to 20 mg once a day in patients with rheumatoid arthritis, and 20 mg once a day in patients with psoriatic arthritis. The medicine usually starts to have an effect after four to six weeks. Its effect may improve further for up to six months.

How does Leflunomide medac work?

The active substance in Leflunomide medac, leflunomide, is an immunosuppressant. It reduces inflammation by reducing the production of immune cells called 'lymphocytes', which are responsible for inflammation. Leflunomide does this by blocking an enzyme called 'dihydroorotate dehydrogenase', which is necessary for the lymphocytes to multiply. With fewer lymphocytes, there is less inflammation, helping to control the symptoms of arthritis.

How has Leflunomide medac been studied?

Because Leflunomide medac is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Arava. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefit and risk of Leflunomide medac?

Because Leflunomide medac is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as the reference medicine's.

Why has Leflunomide medac been approved?

The CHMP concluded that, in accordance with EU requirements, Leflunomide medac has been shown to have comparable quality and to be bioequivalent to Arava. Therefore, the CHMP's view was that, as for Arava, the benefit outweighs the identified risk. The Committee recommended that Leflunomide medac be given marketing authorisation.

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

A risk management plan has been developed to ensure that Leflunomide medac 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 Leflunomide medac, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Leflunomide medac:

The European Commission granted a marketing authorisation valid throughout the European Union for Leflunomide medac on 27 July 2010.

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

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 05-2014.