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EPAR summary for the public

Leflunomide ratiopharm

leflunomide

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

What is Leflunomide ratiopharm?

Leflunomide ratiopharm is a medicine that contains the active substance leflunomide. It is available as white round tablets (10 and 20 mg).

Leflunomide ratiopharm is a 'generic medicine'. This means that Leflunomide ratiopharm 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 ratiopharm used for?

Leflunomide ratiopharm 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 ratiopharm used?

Leflunomide ratiopharm 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 ratiopharm, and regularly during treatment.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Leflunomide ratiopharm treatment 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 ratiopharm work?

The active substance in Leflunomide ratiopharm, 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 ratiopharm been studied?

The applicant presented data on experimental models from the scientific literature.

Because Leflunomide ratiopharm 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 benefits and risks of Leflunomide ratiopharm?

Because Leflunomide ratiopharm 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 ratiopharm been approved?

The CHMP concluded that, in accordance with EU requirements, Leflunomide ratiopharm 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 ratiopharm be given marketing authorisation.

Other information about Leflunomide ratiopharm

The European Commission granted a marketing authorisation valid throughout the European Union for Leflunomide ratiopharm on 29 November 2010.

The full EPAR for Leflunomide ratiopharm can be searched for on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Leflunomide ratiopharm, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2015.