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EPAR summary for the public

Leflunomide Teva

leflunomide

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

What is Leflunomide Teva?

Leflunomide Teva is a medicine that contains the active substance leflunomide. It is available as tablets (white and round: 10 mg; dark beige and triangular: 20 mg).

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

Leflunomide Teva is used to treat adults with active rheumatoid arthritis (an immune system disease causing inflammation of the joints).

The medicine can only be obtained with a prescription.

How is Leflunomide Teva used?

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

Leflunomide Teva 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. The medicine

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usually starts to have an effect after four to six weeks. Its effect may improve further for up to six months.

How does Leflunomide Teva work?

The active substance in Leflunomide Teva, 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 Teva been studied?

Because Leflunomide Teva 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 Teva?

Because Leflunomide Teva is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Leflunomide Teva been approved?

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

Other information about Leflunomide Teva

The European Commission granted a marketing authorisation valid throughout the European Union for Leflunomide Teva to TEVA Pharma B.V. on 10 March 2011. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Leflunomide Teva 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 Teva, 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 01-2011.