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EPAR summary for the public

Repso

leflunomide

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

What is Repso?

Repso 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).

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

Repso 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 Repso used?

Repso 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 Repso, and regularly during treatment.

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Repso 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 Repso work?

The active substance in Repso, 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 Repso been studied?

Because Repso 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 Repso?

Because Repso 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 Repso been approved?

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

Other information about Repso

The European Commission granted a marketing authorisation valid throughout the European Union for Repso to TEVA Pharma B.V. on 14 March 2011. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Repso 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 Repso, 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.

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