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EPAR summary for the public

Jylamvo

methotrexate

This is a summary of the European public assessment report (EPAR) for Jylamvo. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Jylamvo.

For practical information about using Jylamvo, patients should read the package leaflet or contact their doctor or pharmacist.

What is Jylamvo and what is it used for?

Jylamvo is an anti-inflammatory and cancer medicine used to treat the following conditions:

- active rheumatoid arthritis (a disease causing inflammation in joints) in adults;
- severe juvenile idiopathic arthritis (inflammation of joints in children) in patients from 3 years of age when NSAIDs (non-steroidal anti-inflammatory drugs) have not worked well enough;
- severe disabling psoriasis (a disease causing red, scaly patches on the skin) in adults when other treatments have not worked well enough;
- severe psoriatic arthritis (inflammation of joints that occurs in patients with psoriasis) in adults;
- acute lymphoblastic leukaemia (ALL), a cancer of white blood cells, in adults and children over the age of 3 years.

Jylamvo is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' (in this case Methotrexat Lederle) containing the same active substance (methotrexate). The difference between Jylamvo and Methotrexat Lederle is that, whereas the latter is a solution for injection, Jylamvo is available as a solution to be taken by mouth.

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How is Jylamvo used?

Jylamvo can only be obtained with a prescription and should be prescribed by doctors with experience with methotrexate and the way it works.

Jylamvo is available as an oral solution. When used for inflammatory conditions it is taken once a week, on the same day each week. The dose depends on the condition it is being used to treat, how the patient responds to treatment and, in the case of children, on the body surface area. In most cases, Jylamvo is used for long-term treatment.

When used for ALL, the dose of Jylamvo depends on body surface area (calculated using the patient's height and weight). How often methotrexate is given depends on the other medicines it is used with.

For more information on how to use Jylamvo, see the package leaflet.

How does Jylamvo work?

The active substance in Jylamvo, methotrexate, stops cells from growing by interfering with the production of DNA. This especially affects fast-growing cells such as cancer cells. The way methotrexate works in patients with arthritis and psoriasis is not completely understood, but the benefits of methotrexate are thought to be due to its ability to reduce inflammation and suppress an overactive immune system.

How has Jylamvo been studied?

The company provided data from the published literature on the benefits and risks of methotrexate in the approved uses.

As for every medicine, the company provided studies on the quality of Jylamvo. The company also carried out studies that showed that it is 'bioequivalent' to other methotrexate medicines used to treat inflammatory conditions and ALL (Methotrexat Lederle and Ebetrexat tablets). Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Jylamvo?

Because Jylamvo is a hybrid medicine and is bioequivalent to Methotrexat Lederle and Ebetrexat tablets, its benefits and risks are taken as being the same as the benefits and risks of those medicines.

In addition, there is a risk that patients may make mistakes when measuring the amount of solution they need to take and educational material will be provided to prevent this.

Why is Jylamvo approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Jylamvo has shown to have comparable quality and to be bioequivalent to the methotrexate-containing medicines Methotrexat Lederle and Ebetrexat. Therefore, the CHMP's view was that the benefit outweighs the identified risk. The Committee recommended that Jylamvo be approved for use in the EU.

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

The company that markets Jylamvo will supply a guide for healthcare professionals to help them prescribe the medicine correctly and advise their patients on the correct use of the medicine to avoid medication errors.

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

Other information about Jylamvo

The European Commission granted a marketing authorisation valid throughout the European Union for Jylamvo on 29 March 2017.

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

This summary was last updated in 03-2017.