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Jylamvo (*methotrexate*)

An overview of Jylamvo and why it is authorised in the EU

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 (an inflammatory 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 contains the active substance methotrexate.

Jylamvo is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, but Jylamvo is given in a different way. The reference medicine for Jylamvo is Methotrexat Lederle injection.

How is Jylamvo used?

Jylamvo is available as a liquid to be taken by mouth and it can only be obtained with a prescription. It should be prescribed only by doctors with expertise in the use of methotrexate and a full understanding of the risks of methotrexate treatment.

For inflammatory conditions it is taken once a week, on the same day each week. The doctor may check with the patient or the patient's carer that the medicine can reliably be taken once a week. The dose that the patient takes each week depends on which inflammatory condition it is being used for, how well the treatment is working and, in the case of children, on the child's height and weight. In most cases, methotrexate medicines are used for long-term treatment.

For acute lymphoblastic leukaemia, the dose of Jylamvo depends on the patient's height and weight. How often methotrexate is given depends on the other medicines it is used with.

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For more information about using Jylamvo, see the package leaflet or contact your doctor or pharmacist.

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.

What benefits of Jylamvo have been shown in studies?

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 risks associated with Jylamvo?

The most common side effects with Jylamvo (which may affect more than 1 in 10 people) are effects in the digestive system (such as inflammation of the lining of the mouth, indigestion, belly pain, feeling sick and loss of appetite) and blood tests showing changes in the liver. The most serious side effects include reduced production of blood cells, damage to the lung, liver, kidneys and nerves, thromboembolism (problems caused by clots in blood vessels), and severe allergic and skin reactions.

Jylamo must not be used in patients who abuse alcohol or those with liver or severe kidney problems, blood disorders, weakened immune system (body defences), severe or long-term infections such as tuberculosis and HIV infection, mouth ulcers, inflammation in the mouth, and ulcers in the digestive system. It must not be used if the patient is breastfeeding or is receiving live vaccines.

For the full list of side effects and restrictions of Jylamvo, see the package leaflet.

Why is Jylamvo authorised in the EU?

The European Medicines Agency decided that Jylamvo was of comparable quality and was bioequivalent to the methotrexate-containing medicines Methotrexat Lederle and Ebetrexat. The Agency therefore decided that Jylamvo's benefits are greater than its risks and it can be authorised 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 and a patient alert card, on how to use the medicine correctly and how to avoid medication errors. The company will also send out follow-up questionnaires for dosing errors that result in overdose.

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.

As for all medicines, data on the use of Jylamvo are continuously monitored. Side effects reported with Jylamvo are carefully evaluated and any necessary action taken to protect patients.

Other information about Jylamvo

Jylamvo received a marketing authorisation valid throughout the EU on 29 March 2017.

Further information on Jylamvo can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/jylamvo.

This overview was last updated in 10-2019.