



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Jylamvo (methotrexate oral solution): healthcare professionals to receive educational guide to ensure medicine is used correctly

Healthcare professionals should carefully explain to patients when and how to take their dose

Healthcare professionals expected to prescribe and dispense Jylamvo will be given an educational guide to ensure that the medicine is used correctly. Jylamvo, an oral solution containing methotrexate, is used to treat arthritis and the skin disease psoriasis, as well as a type of blood cancer called acute lymphoblastic leukaemia (ALL).

The educational guide will advise healthcare professionals that for arthritis and psoriasis Jylamvo must be taken once a week. Only for ALL, the medicine can be taken more frequently. It is important that healthcare professionals carefully explain to patients when and how they should take their dose. If the medicine is used for psoriasis or arthritis and is inadvertently taken once a day instead of once a week, this could lead to serious harm.

It is also important that patients are carefully instructed on how to withdraw a dose from the bottle using the syringe provided. Any mistakes in measuring the dose could lead to patients receiving too much or too little of the medicine potentially with serious consequences.

Information for patients and carers

- Jylamvo is available as an oral solution that contains 2 mg of methotrexate per ml.
- For arthritis and skin diseases, Jylamvo must be taken once a week only, on the same day each week. A typical dose will range from 7.5 mg (3.75 ml) to 25 mg (12.5 ml) once a week. Methotrexate is never taken every day for arthritis or skin diseases.
- Your doctor, nurse or pharmacist will explain you how to withdraw the required dose using the syringe provided. Only use the syringe provided with Jylamvo to withdraw your dose. Guidance on the amount to withdraw for the different doses in mg is given in the table below:



Jylamvo (methotrexate 2mg/ml)

Dose in mg	5 mg	7.5 mg	10 mg	15	20 mg	25 mg
Amount in ml to be withdrawn	2.5 ml	3.75 ml	5 ml	7.5 ml	10 ml	12.5 ml

- For acute lymphoblastic leukaemia (ALL), the dose is usually higher and you may need to take Jylamvo more frequently. You should follow your healthcare professional's instructions.
- If you have any signs or symptoms of overdose contact your doctor immediately. These include: bleeding, unusual feeling of weakness, ulcers in the mouth, feeling sick, vomiting, black or bloody stools, coughing up blood or vomiting blood and a reduced urine production.
- If you have any questions about your treatment, speak to your doctor, nurse or pharmacist.

Information for healthcare professionals

- Jylamvo is available as an oral solution that contains 2 mg/ml of methotrexate.
- Patients should be counselled on taking the correct dose correctly: for arthritis and psoriasis, Jylamvo must be taken once a week only, on the same day each week. Methotrexate is never taken every day for arthritis or skin diseases. For acute lymphoblastic leukaemia (ALL), the dose is usually higher and given more frequently.
- An oral syringe is provided with Jylamvo and it is important that only this syringe is used to withdraw the dose. The syringe is graduated in ml while the dose is expressed in mg. When prescribing Jylamvo, doctors should always prescribe the dose in mg and ml.
- Healthcare professionals should assess each patient to determine whether they are able to measure the dose correctly. Only after such an assessment should patients start to self-administer Jylamvo at home.
- With every prescription patients should be reminded on how to measure the dose correctly.
- Patients should be monitored for signs and symptoms of overdose, such as bleeding, unusual feeling of weakness, ulcers in the mouth, feeling sick, vomiting, black or bloody stools, coughing up blood or vomiting blood and reduced urine output.

More about the medicine

Jylamvo is a medicine that is used for the treatment of the following inflammatory conditions:

- active rheumatoid arthritis, an inflammatory joint disease;
- severe juvenile idiopathic arthritis (JIA), a joint disease in children;
- severe disabling psoriasis, a disease causing red, scaly patches on the skin.
- severe psoriatic arthritis, an inflammatory joint disease that occurs in patients with psoriasis.

Jylamvo is also used to treat adults and children over the age of 3 years who have acute lymphoblastic leukaemia (ALL), a cancer of white blood cells called lymphoblasts.

More information about Jylamvo can be found on the Agency's website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003756/human_med_002083.jsp