Jylamvo® (methotrexate) Oral Solution

Instructions for Using JYLAMVO®

Each pack of JYLAMVO® contains a bottle of medicine with a cap, a bottle neck adaptor, and a white dosing syringe. JYLAMVO is a hazardous drug subject to special handling instructions. Always use the dosing syringe provided in the pack and disposable gloves when handling JYLAMVO®.



Carefully follow the instructions below:



1

Shake bottle, remove cap, and push adaptor into the top of the bottle.



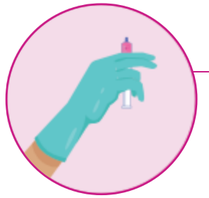
2

Push tip of dosing syringe into the hole in the adaptor and turn bottle upside down.



3

Pull syringe plunger back **slowly** until the **widest** part of the white syringe plunger lines up with the black mark on syringe indicating prescribed dose. If there are air bubbles, push medicine back into the bottle and redraw until no bubbles remain.



4

Return bottle to an upright position, remove syringe from the adaptor, and hold the syringe by the barrel.



5

Check syringe for correct dose.



6

Sit up or stand before taking medicine. Place the syringe tip in your mouth and direct it to the inside of your cheek. Push the plunger slowly until it clicks.



7

Swallow medicine and then drink water.



8

Put the cap back on the bottle **leaving the adaptor in place** and close it tightly.



9

Immediately after use, wash the syringe with warm, soapy water. Draw the plunger in and out under water to remove medicine. Remove plunger, wash thoroughly, and rinse with cold water. Dry with a paper towel. Ensure all parts are fully dry before reuse.

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How should I take JYLAMVO®?

- JYLAMVO® is for use by mouth only (oral use).
- Take JYLAMVO® exactly as prescribed by your healthcare provider.
- If you take too much JYLAMVO®, call your healthcare provider or go to your nearest emergency room.
- If you miss taking a dose of JYLAMVO®, call your healthcare provider for instructions about when to take your next dose.
- Discuss with your healthcare provider if you should or should not take folic acid/folinic acid supplements and/or what form(s) of birth control/contraception you can use during treatment.

If you are taking JYLAMVO® for severe psoriasis or rheumatoid arthritis treatment: Take your JYLAMVO® dose 1 time a week, not every day.

If you are taking JYLAMVO® for cancer treatment: Follow your healthcare provider's instructions about how much JYLAMVO® to take and when to take it.

Tell your healthcare provider if you develop any unusual side effects during treatment with JYLAMVO®.

How should I store JYLAMVO®?

- Store bottle at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep the cap on the bottle tightly closed.
- Store dosing syringe in a clean, dry place when not in use.
- Use JYLAMVO® within 3 months of opening. Discard any remaining medicine afterward. Consult your pharmacist on proper disposal of the medicine, bottle, and syringe. Do not discard it in wastewater or household waste.
- Keep JYLAMVO® out of the reach of children.

IMPORTANT SAFETY INFORMATION

WARNING: EMBRYO-FETAL TOXICITY, HYPERSENSITIVITY REACTIONS, and SEVERE ADVERSE REACTIONS

- **Methotrexate can cause embryo-fetal toxicity, including fetal death. For non-neoplastic diseases, JYLAMVO® is contraindicated in pregnancy. For neoplastic diseases, advise females and males of reproductive potential to use effective contraception during and after treatment with JYLAMVO®.**
- **JYLAMVO® is contraindicated in patients with a history of severe hypersensitivity reactions to methotrexate, including anaphylaxis.**
- **Serious adverse reactions, including death, have been reported with methotrexate. Closely monitor for infections and adverse reactions of the bone marrow, gastrointestinal tract, liver, lungs, skin, and kidneys. Withhold or discontinue JYLAMVO® as appropriate.**

For more information, please visit shorlaoncology.com/product/jylamvo

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Patient Information
JYLAMVO® (Jye lam voe)
(methotrexate)
oral solution

What is the most important information I should know about JYLAMVO®?
JYLAMVO can cause serious side effects that may be severe and lead to death, including:
- **Harm to an unborn baby, including birth defects or death of an unborn baby**.

Females who can become pregnant:
Your healthcare provider should do a pregnancy test before you start taking JYLAMVO to see if you are pregnant.
- o **If you are being treated for a medical condition other than cancer, do not take JYLAMVO if you are pregnant. See "Who should not take JYLAMVO?"**
- o If you are taking JYLAMVO to treat your cancer**,** you and your healthcare provider will decide if you will take JYLAMVO if you are pregnant.
- o Use effective birth control (contraception) during treatment and for **6 months** after your final dose of JYLAMVO. Ask your healthcare provider what forms of birth control you can use during this time.
- o **Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with JYLAMVO.**

Males with female partners who are able to become pregnant:
- o Use effective birth control during treatment and for **at least 3 months** after your final dose of JYLAMVO.
- o **Tell your healthcare provider right away if your female partner becomes pregnant during treatment with JYLAMVO.**

- **Severe allergic reactions.** Severeallergicreactionscanhappen with JYLAMVO.Signsandsymptomsofasevereallergic reaction may include:

- o skin rash, itching and hives
- o swelling of the face, lips, tongue, or throat
- o dizziness
- o trouble breathing
- o wheezing
- o fast heart rate
- o feeling faint
- o stomach-area pain
- o vomiting or diarrhea

Do not take JYLAMVO if you have had a severe allergic reaction to methotrexate in the past.
Get medical help right away if you develop any of the signs or symptoms of a severe allergic reaction listed above.

- **Decreased blood cell counts.** JYLAMVO can affect your bone marrow and cause decreases in red blood counts, white blood cell counts, and platelets that can be severe and life-threatening.
  - o Your healthcare provider will check your blood cell counts when you start and during treatment with JYLAMVO.

Call your healthcare provider right away if you develop any of the following:
- o a new fever
- o symptoms of infection
- o easy bruising orbleedingthatwillnot stop(persistentbleeding)

- **Severe stomach and intestine problems (gastrointestinal) problems.**
  - o Diarrhea,vomiting,nausea,andmouth sorescanhappeninpeoplewhotakeJYLAMVO.
  - o **Inflammation of the intestine with severe bleeding and a tear in the intestinal wall (perforation) have happened with methotrexate and cause death.**
  - o People who have stomach ulcers (peptic ulcer disease)orulcerative colitis(UC) havea greater riskof developingsevere stomach or intestine problems with JYLAMVO.

Tell your healthcare provider if you develop new or worsening diarrhea, vomiting, or mouth sores during treatment with JYLAMVO.
Tell your healthcare provider right away if you develop high fever, shaking chills (rigors), pain in your stomach-area (abdomen) that will not go away or is severe, severe constipation, if you are vomiting blood or have blood in your stools.

- **Liver problems.** JYLAMVOcan causesevereliver problems includingliver scarring(fibrosis),cirrhosis,andliverfailure thatmaynot getbetter (possibly irreversible)andcan cause death.
  - o **In people with psoriasis** who takeJYLAMVO, liverfibrosis or cirrhosis mayhappen withoutany symptomsor abnormal liver tests. The risk for liver problems in people with psoriasis increaseswith theamount ofJYLAMVOtaken over time.
  - o Your healthcare provider will do tests to monitor your liver function before you start and during treatment with JYLAMVO.

Tell your healthcare provider if you get any signs or symptoms of liver problems during treatment with JYLAMVO, including:

- o tiredness
- o easy bleeding or bruising
- o loss of appetite
- o nausea
- o difficulty thinkingclearly
- o swelling in your legs, feet or ankles
- o weight loss
- o itchy skin
- o yellowing of your skin or the white part of your eyes
- o weakness

- **Lung problems.** Lungproblems canhappensuddenly(acute)with JYLAMVO or they can developover a long period-of-time (chronic). Lungproblemsmaynotgetbetter(possiblyirreversible)andcan cause death.
Tell your healthcare provider if you have any new or worsening symptoms including: cough (especially a dry cough), fever, or trouble breathing.

- **Severe skin reactions.** Severe skin reactions canhappen withJYLAMVOandcanlead todeath.
  - o **In people with psoriasis:** Your psoriasis maygetworse ifyouareexposedtosunlightorothertypes ofultravioletlight.
  - o JYLAMVO cancause reactivation of skin reactions that can happenafterradiation therapy (radiation recall dermatitis) and cause sunburn to come back (photodermatitis).

Limit sunlight exposure during treatment with JYLAMVO. Use sunscreen and wear protective clothing when you will be exposed tosunlightduring treatment with JYLAMVO.
Tell your healthcare provider right away about any new or worsening skin rash during treatment with JYLAMVO.

- **Kidney problems. Kidney problems can happen with JYLAMVO, including kidney failure which can happen suddenly (acute) and may not go away (irreversible).**
Your healthcare provider willcheck yourkidney functionbeforeyoustart and duringtreatmentwithJYLAMVO.
Tell your healthcare provider right away if you developany signsorsymptomsofkidneyproblems,including:

- o a big change (either increase or decrease) in the amount of urine you produce
- o swelling in your legs, ankles or feet
- o shortness of breath
- o tiredness
- o weight gain

- **Risk of death from taking JYLAMVO the wrong way**. JYLAMVO is taken 1 time each week for rheumatoid arthritis, polyarticular juvenile idiopathic arthritis (pJIA), and severe psoriasis. Deaths have happened when JYLMAVO was taken every day instead of 1 time weekly. See "**How should I take JYLAMVO?**" for instructions on taking this medicine correctly.

See **"What are the possible side effects of JYLAMVO"** for more information about side effects.

What is JYLAMVO?
JYLAMVO is a prescription medicine used:
- in combination with other chemotherapy medicines in adults and children, for maintenance treatment of acute lymphoblastic leukemia (ALL)
- to treat adults with mycosis fungoides (cutaneous T-cell lymphoma)
- in combination with other therapies to treat adults with non-Hodgkin lymphoma that has come back (relapsed) or did not respond to previous treatment (refractory)
- to treat adults with rheumatoid arthritis
- to treat children with polyarticular juvenile idiopathic arthritis (pJIA)
- to treat adults with severe psoriasis

It is not known if JYLAMVO is safe and effective in children for the treatment of any medical condition other than ALL as part of a combination regimen used for maintenance therapy of their cancer, and pJIA.
It is not known if JYLAMVO is safe in people with liver problems.

Do not take JYLAMVO if you:
- are pregnant and are being treated or will be treated with JYLAMVO for rheumatoid arthritis, pJIA, severe psoriasis or for any medical condition other than cancer. JYLAMVO can cause harm to an unborn baby, including birth defects or death of an unborn baby. See **"What is the most important information I should know about JYLAMVO?"**
- have or had a severe allergic reaction to JYLAMVO or any other medicine containing methotrexate. See "**What is the most important information I should know about JYLAMVO?"** See the end of this Patient Information leaflet for a complete list of ingredients in JYLAMVO.

Before taking JYLAMVO tell your healthcare provider about all of your medical conditions, including if you:
- have kidney problems or are receiving dialysis treatments.
- have liver problems.
- drink alcohol-containing beverages and, during treatment with JYLAMVO, if there are any changes in the amount of alcoholic beverages you drink.
- have fluid in your stomach-area (ascites).
- have lung problems or fluid in your lungs (pleural effusion).
- plan to have any surgeries with general anesthesia, including dental surgery.
- have stomach ulcers (peptic ulcer disease).
- have ulcerative colitis.
- have recently received or are scheduled to receive a vaccine. You should not receive live vaccines during treatment with JYLAMVO. These vaccines may not be safe or may not work as well during treatment with JYLAMVO.
- are breastfeeding or plan to breastfeed. JYLAMVO may pass into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of JYLAMVO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. JYLAMVO and certain other medicines can affect each other and cause serious side effects. Do not start or change any medicines unless you have talked to your healthcare provider and your healthcare provider has told you it is safe. Know all the medicines that you take and keep a list of them with you at all times to show healthcare providers and pharmacists.

How should I take JYLAMVO?
- JYLAMVOisforusebymouth only (oral use).
- **Take JYLAMVO exactly as prescribed by your healthcare provider.** Your dose of JYLAMVOandwhenyoutakeitwill dependontheconditionthat is being treated.
- **Do not** takemoreJYLAMVO than prescribed. **Do not** change your dose of JYLAMVO unless yourhealthcareprovidertells you to.
- **Taking more JYLAMVO than prescribed or taking JYLAMVO more often than prescribed, can lead to severe side effects and cause death. If you are not sure how often to take JYLAMVO, ask your healthcare provider or pharmacist.**
- **If you take too much JYLAMVO call your healthcare provider or go to your nearest hospital emergency room right away. You will need to receive a medicine as soon as possible to help reduce side effects that could be severe and could cause death.**
- **If you miss taking a dose of JYLAMVO, call your healthcare provider for instructions about when to take your next dose of JYLAMVO.**

If you are taking JYLAMVO for treatment of severe psoriasis, rheumatoid arthritis or polyarticular juvenile idiopathic arthritis:
- **Take your JYLAMVO dose 1 time each week (on the same day of the week).**
  - o **Do not take JYLAMVO every day. Severe side effects and death have happened in people who have mistakenly taken JYLAMVO every day instead of 1 time each week.**
- **Take a folic acid or folinic acid supplement every day during treatment with JYLAMVO,** as instructed by your healthcare provider, to help reduce the chance of developing certain side effects, such as mouth sores.

If you are taking JYLAMVO to treat your cancer:
- **Follow your healthcare provider's instructions about how much JYLAMVO to take and when to take it.**
- **Do not take folic acid or folinic acid** during treatment with JYLAMVO unless your healthcare provider tells you to. Taking folic acid or folinic acid with JYLAMVO may make your JYLAMVO treatment less effective.

Instructions for Using JYLAMVO
Each pack of JYLAMVO contains a bottle of medicine with a cap, a bottle neck adaptor, and a white dosing syringe. **Always use the dosing syringe provided in the pack to take JYLAMVO**. A household teaspoon is not an accurate measuring device.

Note: the dosing syringe measures the amount of oral solution in mL and JYLAMVO contains 2 mg of methotrexate in 1 mL of solution.
Read and carefully follow the instructions below:
1. **Put on disposable gloves** before handling JYLAMVO.
2. Shake the bottle.
3. Remove the bottle cap and push the adaptor firmly into the top of the bottle.
4. Push the tip of the dosing syringe into the hole in the adaptor.
5. Turn the bottle upside down.
6. Pull the syringe plunger back **slowly** so that the medicine is drawn from the bottle into the syringe until the **widest** part of the white syringe plunger is lined up to the black syringe marking of the prescribed dose. **Do not** measure to the narrow tip of the plunger. If there are air bubbles in the syringe, use the syringe plunger to push the medicine back into the bottle then draw the medicine into the syringe again until there are no more air bubbles.
7. Turn the bottle back upright and carefully remove the syringe from the adaptor, holding the syringe by the barrel rather than the plunger.
8. Check that the dose in the syringe is correct.
9. Make sure that you are sitting up or standing before taking the medicine.
10. Gently place the tip of the syringe in your mouth and direct it to the inside of your cheek.
11. Slowly and gently push the plunger down to gently squirt the medicine into the inside of your cheek. **Do not** push down on the plunger too hard or squirt the medicine to the back of the mouth or throat as this may cause choking. The plunger should be pushed down gently and completely until it clicks into place.
12. Remove the syringe from your mouth.
13. Swallow the medicine and then drink some water, making sure no medicine is left in the mouth.
14. Put the cap back on the bottle **with the adaptor left in place**. Make sure that the cap is tightly closed.
15. Wash the syringe immediately after use with warm, soapy water and rinse well. The syringe should be held under water and the plunger drawn in and out several times until all of the medicine is removed from inside the syringe including the tip. Remove the plunger from the syringe barrel and wash both parts well in the warm, soapy water. Each part should then be rinsed well under **cold** water and any extra water shaken off before wiping dry with a clean paper towel. The plunger and barrel should be stored in a clean dry container with the medicine. All parts of the syringe should be completely dry before putting the plunger back into the syringe and using it for the next dose.

What are the possible side effects of JYLAMVO?
JYLAMVO can cause serious side effects that may be severe and lead to death including:
- See **"What is the most important information I should know about JYLAMVO?"**
- **Serious infections.** People whotake methotrexate have an increased risk of developinginfections that can be life-threatening orcause death. These infections may include: bacterial, fungal, or viral infections, including Pneumocystis jiroveci pneumonia, invasive fungal infections, hepatitis B infection that comes back (reactivation), tuberculosis infection thatmay be newor reactivation, and Herpes zoster orcytomegalovirus (CMV) that spreadsthroughout thebody (disseminated)**.**
Tell your healthcare provider right away if you develop a new fever or if you have any symptoms of infection during treatment with JYLAMVO.
- **Brain and spinal cord (nervous system) problems.** Methotrexatecan causenervous system problemsthat can be severe andlastfor a short time orlast for a long time. These nervous system problems canget progressivelyworse, may not get better (irreversible), and can cause death. The risk for a certain nervous system problem called leukoencephalopathy is increased in people who have had radiation treatment to their head (cranial radiation) in the past.
Tell your healthcare provider about any new nervous system symptoms that you develop during treatment with JYLAMVO.
- **New (secondary) cancers.** New (secondary) cancers can happen in people who take JYLAMVO.
  - o In people with psoriasis, the risk of new skin cancers is increased with JYLAMVO and further increased if you take the medicine cyclosporine after receiving treatment with JYLAMVO.
  - o Certain blood cancers can happen during treatment with JYLAMVO. In some cases, these blood cancers may completely go away (regress completely) after JYLAMVO is stopped.
- **Tumor lysis syndrome (TLS).** TLS is caused by the fast breakdown of cancer cells. TLS can cause kidney failure and the need for dialysis treatment, abnormal heart rhythm, seizure, and sometimes death. Your healthcare provider may do blood tests to check you for TLS if you are receiving JYLAMVO as a cancer treatment.
- **Possible fertility problems (infertility) in males and females.** JYLAMVO can cause fertility problems in males and females, and can cause sperm production to stop in males, and menstrual problems in females. Males may not be able to father a child. Females may not be able to become pregnant. It is not known if your fertility may return. Talk with your healthcare provider about your risk for infertility if this is a concern for you.

The most common side effects of JYLAMVO include:
- mouth sores
- low white blood cells. **See "What is the most important information I should know about JYLAMVO?"**
- nausea
- upset stomach

These are not all the possible side effects of JYLAMVO. Ask your healthcare provider or pharmacist for more information.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800- FDA-1088.

How should I store JYLAMVO?
- Store the JYLAMVO bottle at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep JYLAMVO tightly closed with the cap on the bottle.
- Store the dosing syringe in a clean, dry place when not in use.
- Use JYLAMVO within 3 months of first opening the bottle. After 3 months throw away (dispose of) any remaining medicine. Ask the pharmacist how to throw away (dispose of) unused medicine, the bottle and the dosing syringe. This medicine should notbe disposed of in wastewater or household waste.

Keep JYLAMVO and all medicines out of the reach of children.

General information about the safe and effective use of JYLAMVO.
Medicinesare sometimes prescribed forpurposes other than those listed in a Patient Information leaflet. Do not use JYLAMVO for a condition for which it was not prescribed. Do not give JYLAMVO to other people, even if they have the same symptoms that you have. It may harm them. This Patient Information leaflet summarizes the most important information about JYLAMVO. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about JYLAMVO that is written for health professionals.

What are the ingredients in JYLAMVO?
Active Ingredient: methotrexate
Inactive Ingredients: citric acid, ethylparaben, glycerin, methylparaben sodium, orange flavoring powder, polyethylene glycol, purified water, sodium citrate and sucralose.

Manufactured By:
SGSUnitedKingdom Ltd., Deeside, UK
Distributed By:
ShorlaOncologyInc., Cambridge, MA 02142, USA

Version: JYLPL009

ThisPatientInformationhas been approved by theU.S. Food andDrug Administration

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Date:	26-AUG-2026	Time :	20:02
Title	19215_Jylamvo_PI_US		
Component Type	Leaflet		
Proof N°	v2	Perigord N°	19215
Item N°	XXXXXX	Barcode N°	N/A
Market	US	Size (mm)	475 x 297 mm
Client	Shorla Pharma Limited	Min point size	7 pt
Printing Colours (1)	Pro. Black		
Technical colors	Keyline		