

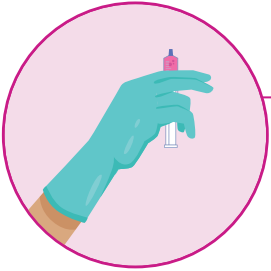






Instructions for Using JYLAMVO®

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 and disposable gloves when handling JYLAMVO®.**



Carefully follow the instructions below:

-  Shake bottle, remove cap, and push adaptor into the top of the bottle.
-  Push tip of dosing syringe into the hole in the adaptor and turn bottle upside down.
-  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.
-  Return bottle to an upright position, remove syringe from the adaptor, and hold the syringe by the barrel.
-  Check syringe for correct dose.
-  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.
-  Swallow medicine and then drink water.
-  Put the cap back on the bottle leaving the adaptor in place and close it tightly.
-  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.

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.**

Patient Information JYLAMVO® (Jye lam voe) (methotrexate) oral solution																										
<p>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:</p> <ul style="list-style-type: none">• Your healthcare provider should do a pregnancy test before you start taking JYLAMVO® to see if you are pregnant.<ul style="list-style-type: none">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®. <p>Males with female partners who are able to become pregnant:</p> <ul style="list-style-type: none">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®. <p>Severe allergic reactions. Severe allergic reactions can happen with JYLAMVO®. Signs and symptoms of a severe allergic reaction may include:</p> <table><tr><td>• skin rash, itching and hives</td><td>• fast heart rate</td></tr><tr><td>• swelling of the face, lips, tongue, or throat</td><td>• feeling faint</td></tr><tr><td>• dizziness</td><td>• stomach-area pain</td></tr><tr><td>• trouble breathing</td><td>• vomiting or diarrhea</td></tr><tr><td>• wheezing</td><td></td></tr></table> <p>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.</p> <ul style="list-style-type: none">• Your healthcare provider will check your blood cell counts when you start and during treatment with JYLAMVO®. <p>Call your healthcare provider right away if you develop any of the following:</p> <ul style="list-style-type: none">• a new fever• symptoms of infection• easy bruising or bleeding that will not stop (persistent bleeding) <p>Severe stomach and intestine problems (gastrointestinal) problems.</p> <ul style="list-style-type: none">• Diarrhea, vomiting, nausea, and mouth sores can happen in people who take JYLAMVO®.• Inflammation of the intestine with severe bleeding and a tear in the intestinal wall (perforation) have happened with methotrexate and cause death.• People who have stomach ulcers (peptic ulcer disease) or ulcerative colitis (UC) have a greater risk of developing severe stomach or intestine problems with JYLAMVO®. <p>Tell your healthcare provider if you develop new or worsening diarrhea, vomiting, or mouth sores during treatment with JYLAMVO®.</p> <p>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. JYLAMVO® can cause severe liver problems including liver scarring (fibrosis), cirrhosis, and liver failure that may not get better (possibly irreversible) and can cause death.</p> <ul style="list-style-type: none">• In people with psoriasis who take JYLAMVO®, liver fibrosis or cirrhosis may happen without any symptoms or abnormal liver tests. The risk for liver problems in people with psoriasis increases with the amount of JYLAMVO® taken over time.• Your healthcare provider will do tests to monitor your liver function before you start and during treatment with JYLAMVO®. <p>Tell your healthcare provider if you have any signs or symptoms of liver problems during treatment with JYLAMVO®, including:</p> <table><tr><td>• tiredness</td><td>• swelling in your legs, feet or ankles</td></tr><tr><td>• easy bleeding or bruising</td><td>• weight loss</td></tr><tr><td>• loss of appetite</td><td>• itchy skin</td></tr><tr><td>• nausea</td><td>• yellowing of your skin or the white part of your eyes</td></tr><tr><td>• difficulty thinking clearly</td><td>• weakness</td></tr></table> <p>Lung problems. Lung problems can happen suddenly (acute) with JYLAMVO® or they can develop over a long period-of-time (chronic). Lung problems may not get better (possibly irreversible) and can cause death. Tell your healthcare provider if you have any new or worsening symptoms including: cough (especially a dry cough), fever, or trouble breathing.</p> <p>Severe skin reactions. Severe skin reactions can happen with JYLAMVO® and can lead to death.</p> <ul style="list-style-type: none">• In people with psoriasis: Your psoriasis may get worse if you are exposed to sunlight or other types of ultraviolet light.• JYLAMVO® can cause reactivation of skin reactions that can happen after radiation therapy (radiation recall dermatitis) and cause sunburn to come back (photodermatitis). <p>Limit sunlight exposure during treatment with JYLAMVO®. Use sunscreen and wear protective clothing when you will be exposed to sunlight during treatment with JYLAMVO®.</p> <p>Tell your healthcare provider right away about any new or worsening skin rash during treatment with JYLAMVO®.</p> <p>Kidney problems. Kidney problems can happen with JYLAMVO®, including kidney failure which can happen suddenly (acute) and may not go away (irreversible).</p> <p>Your healthcare provider will check your kidney function before you start and during treatment with JYLAMVO®.</p> <p>Tell your healthcare provider right away if you have any signs or symptoms of kidney problems, including:</p> <table><tr><td>• a big change (either increase or decrease) in the amount of urine you produce</td><td>• shortness of breath</td></tr><tr><td>• swelling in your legs, ankles or feet</td><td>• tiredness</td></tr><tr><td></td><td>• weight gain</td></tr></table> <p>See “What are the possible side effects of JYLAMVO®” for more information about side effects.</p>	• skin rash, itching and hives	• fast heart rate	• swelling of the face, lips, tongue, or throat	• feeling faint	• dizziness	• stomach-area pain	• trouble breathing	• vomiting or diarrhea	• wheezing		• tiredness	• swelling in your legs, feet or ankles	• easy bleeding or bruising	• weight loss	• loss of appetite	• itchy skin	• nausea	• yellowing of your skin or the white part of your eyes	• difficulty thinking clearly	• weakness	• a big change (either increase or decrease) in the amount of urine you produce	• shortness of breath	• swelling in your legs, ankles or feet	• tiredness		• weight gain
• skin rash, itching and hives	• fast heart rate																									
• swelling of the face, lips, tongue, or throat	• feeling faint																									
• dizziness	• stomach-area pain																									
• trouble breathing	• vomiting or diarrhea																									
• wheezing																										
• tiredness	• swelling in your legs, feet or ankles																									
• easy bleeding or bruising	• weight loss																									
• loss of appetite	• itchy skin																									
• nausea	• yellowing of your skin or the white part of your eyes																									
• difficulty thinking clearly	• weakness																									
• a big change (either increase or decrease) in the amount of urine you produce	• shortness of breath																									
• swelling in your legs, ankles or feet	• tiredness																									
	• weight gain																									

<p>What is JYLAMVO®? JYLAMVO® is a prescription medicine used:</p> <ul style="list-style-type: none">in combination with other chemotherapy medicines in adults 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 arthritisto treat adults with severe psoriasis <p>JYLAMVO® is not for use in children. It is not known if JYLAMVO® is safe in people with liver problems.</p>
<p>Do not take JYLAMVO® if you:</p> <ul style="list-style-type: none">are pregnant and are being treated or will be treated with JYLAMVO® for rheumatoid arthritis, severe psoriasis or for any disease 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 leaflet for a complete list of ingredients in JYLAMVO®.
<p>Before taking JYLAMVO® tell your healthcare provider about all of your medical conditions, including if you:</p> <ul style="list-style-type: none">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®.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®. <p>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.</p>
<p>How should I take JYLAMVO®?</p> <ul style="list-style-type: none">JYLAMVO® is for use by mouth only (oral use).Take JYLAMVO® exactly as prescribed by your healthcare provider. Your dose of JYLAMVO® and when you take it will depend on the condition that is being treated.Do not take more JYLAMVO® than prescribed. Do not change your dose of JYLAMVO® unless your healthcare provider tells 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 take too much JYLAMVO® call your healthcare provider or go to your nearest hospital emergency room right way. 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®. <p>If you are taking JYLAMVO® for treatment of severe psoriasis or rheumatoid arthritis:</p> <ul style="list-style-type: none">Take your JYLAMVO® dose 1 time each week, not every day. Severe side effects and death have happened in people who mistakenly have 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. <p>If you are taking JYLAMVO® to treat your cancer:</p> <ul style="list-style-type: none">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. <p>Taking folic acid or folinic acid with JYLAMVO® may make your JYLAMVO® treatment less effective.</p>
<p>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:</p> <ol style="list-style-type: none">Put on disposable gloves before handling JYLAMVO®.Shake the bottle.Remove the bottle cap and push the adaptor firmly into the top of the bottle.Push the tip of the dosing syringe into the hole in the adaptor.Turn the bottle upside down.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.Turn the bottle back upright and carefully remove the syringe from the adaptor, holding the syringe by the barrel rather than the plunger.

<ol style="list-style-type: none">Check that the dose in the syringe is correct.Make sure that you are sitting up or standing before taking the medicine.Gently place the tip of the syringe in your mouth and direct it to the inside of your cheek.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.Remove the syringe from your mouth.Swallow the medicine and then drink some water, making sure no medicine is left in the mouth.Put the cap back on the bottle with the adaptor left in place. Make sure that the cap is tightly closed.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.
<p>What are the possible side effects of JYLAMVO®? JYLAMVO® can cause serious side effects that may be severe and lead to death including:</p> <ul style="list-style-type: none">See “What is the most important information I should know about JYLAMVO®?”Serious infections. People who take methotrexate have an increased risk of developing infections that can be life-threatening or cause 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 that may be new or reactivation, and Herpes zoster or cytomegalovirus (CMV) that spreads throughout the body (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. Methotrexate can cause nervous system problems that can be severe and last for a short time or last for a long time. These nervous system problems can get progressively worse, 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®.<ul style="list-style-type: none">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®.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. <p>The most common side effects of JYLAMVO® include:</p> <ul style="list-style-type: none">mouth soreslow white blood cells. See “What is the most important information I should know about JYLAMVO®?”nausea, upset stomach <p>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.</p>
<p>How should I store JYLAMVO®?</p> <ul style="list-style-type: none">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 not be disposed of in wastewater or household waste. <p>Keep JYLAMVO® and all medicines out of the reach of children.</p>
<p>General information about the safe and effective use of JYLAMVO®. Medicines are sometimes prescribed for purposes 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 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.</p>
<p>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.</p> <p>Manufactured By: SGS Quay Pharmaceuticals Ltd., Deeside, UK</p> <p>Distributed By: Shorla Oncology Inc., Cambridge, MA 02142, USA</p>