

Xatmep[®]
(methotrexate)
Oral Solution
2.5 mg/mL

Xatmep is the first and only FDA-approved oral liquid form of a medicine called methotrexate, which is used in the treatment of pediatric patients with ACUTE LYMPHOBLASTIC LEUKEMIA (ALL).*

For more information, visit [Xatmep.com](https://www.Xatmep.com) or call 1-855-379-0382.

This information should not take the place of talking to your doctor about your condition and treatment.

Please see Indications and Important Safety Information inside and accompanying full Prescribing Information, including Boxed Warning, in pocket.

What is Xatmep[®]?

(methotrexate) Oral Solution 2.5 mg/mL

What does a prescription for Xatmep mean for you or your patient?

Xatmep is taken orally, eliminating the need to split or crush tablets, and offering an alternative to vials, needles, and injections.

It also allows you to give doses of the medicine accurately by mouth. Because Xatmep is FDA-approved, you can be sure it's a high-quality product that meets all the requirements of the FDA (Food and Drug Administration) and its CGMPs (Current Good Manufacturing Practices).

How should Xatmep be used?

Xatmep comes as a liquid formulation to be taken **orally one time weekly**. Your doctor will tell you how much Xatmep that you or the patient should take. Do not change the dose of Xatmep unless your doctor tells you to do so.

- The recommended starting dose for Xatmep in ALL is 20 mg/m² given one time weekly. Mistaken daily use has resulted in fatal toxicity.
- Xatmep should be taken at the time and frequency specified by your doctor.

How should Xatmep be measured?

- Always carefully measure the prescribed dose of Xatmep before you or the patient takes it.
- You can ask the pharmacist for **an accurate (mL) dosing device** for dispensing the medication.
- A household teaspoon is NOT an accurate dosing device.
- Make sure the entire prescribed dose of Xatmep is swallowed.

Missed a dose of Xatmep?

- If you or the patient misses a dose of Xatmep, **contact your doctor**. Use the normal amount. Do not use more medicine than your doctor has prescribed.
- If you have questions about Xatmep, ask your doctor or your pharmacist.
- Consult your doctor before making any changes to the dose of medication.

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Xatmep administration and storage.

- Xatmep is convenient to administer and requires no time to prepare.
- **Same potency from first to last dose.**
- Consistent from hospital to home.
- **Store refrigerated** (2°C – 8°C/36°F – 46°F) in a tightly closed container. Patients may store Xatmep either refrigerated (2°C – 8°C/36°F – 46°F) or at room temperature (20°C – 25°C/68°F – 77°F); excursions permitted to 15°C – 30°C/59°F – 86°F. If stored at room temperature, discard after 60 days. Avoid freezing and excessive heat.
- **No shaking necessary** prior to administration.

Xatmep is affordable and accessible.

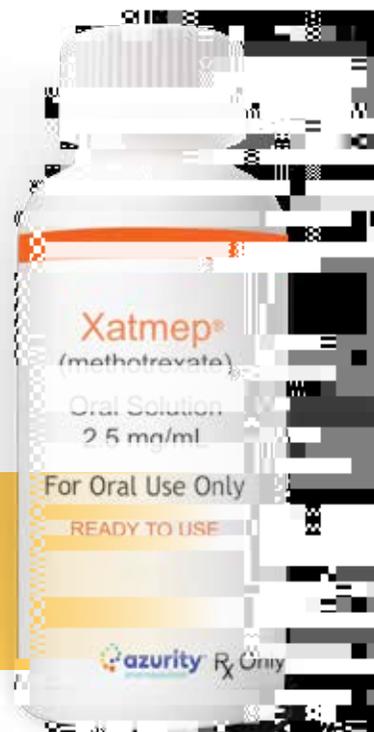
- You may be eligible for coverage by your insurance plan, in which case you may pay no more than \$5 for Xatmep.[†]
- Xatmep is covered by Medicaid.
- Co-pay support programs are available for qualifying patients.
- Available at most pharmacies.

[†]You can learn more about these programs and Eligibility Restrictions, Terms and Conditions at www.Xatmep.com.

Keep this and all medications out of reach of children.

SWEET TASTE

No artificial flavor or dyes



(Pronounced zat´ mep)

What is ALL?

Acute lymphoblastic leukemia (ALL), also called acute “lymphocytic” leukemia, is a cancer of the blood and bone marrow. “Acute” means “having severe symptoms in a short period of time.” “Lymphoblastic” or “lymphocytic” refers to a certain type of abnormal cell growth. And “leukemia” means “cancer of the blood or bone marrow.” ALL is the most common form of cancer diagnosed in children.

In children who develop ALL, the body makes too many white blood cells that normally fight off infection. But they don’t work like normal, and leave less room for healthy blood cells that the body needs.

What causes ALL?

ALL is associated with certain “risk factors” (things that increase the risk of developing a disease) that may possibly determine whether a child develops ALL. These could be “environmental,” meaning from exposure to certain things, or “genetic,” meaning from within the child’s own body.

What are symptoms and signs of ALL?

The symptoms of ALL that are most common include fever and easy bruising or excessive bleeding.

Other symptoms include:

- Small, dark red spots under the skin (from bleeding)
- Painless lumps in the child’s neck, underarms, stomach, or groin
- Pain or a feeling of fullness below the ribs
- Bone or joint pain
- Weakness, feeling tired, or a pale complexion
- Loss of appetite

How is ALL diagnosed?

If a doctor confirms any of the symptoms listed above, and/or suspects ALL, he or she could perform any or all of the following:

- A complete physical exam
- A complete history of the child’s and family’s health
- A test called a complete blood count (CBC) using blood drawn through a needle
- A blood chemistry test, also using blood drawn through a needle
- A bone marrow study, removing a small piece of bone and marrow drawn through a hollow needle, typically from the hipbone or breastbone

How is ALL treated?

The treatment of ALL in children is usually done in three phases. The first is to “kill” leukemia cells in the blood and bone marrow and put the cancer into remission. The next is to intensify the treatment to kill any remaining leukemia cells in the body. And third is the maintenance stage, which is done to kill remaining cells that could cause the cancer to come back.

During the third phase, doctors often prescribe methotrexate [now available as Xatmep™ (methotrexate) Oral Solution 2.5 mg/mL in a ready-to-use oral liquid] as one of a combination of medicines used in maintenance chemotherapy. Periodically, your doctor will want to monitor the patient’s blood to ensure that the right amount of Xatmep is being used.

How can you help your child live with ALL?

ALL is a disease that affects the entire family. Plus, it can affect a child’s social and school activities. To help a child with ALL, both physically and emotionally, consider:

- Getting the best care available
- Learning as much you can about ALL and its treatment
- Talking with, and listening to, your child
- Preparing for changes in appearance (such as hair loss), relationships, feelings, and schedules, like missing school
- Getting your family involved, including brothers and sisters
- Getting support for you and your family members through professional organizations, support groups, and friends
- Staying strong physically and emotionally



Source: Childhood Acute Lymphoblastic Leukemia Treatment (PDQ®)–Patient Version. National Cancer Institute. www.cancer.gov/types/leukemia/hp/child-all-treatment-pdq. Accessed October 3, 2017.

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IMPORTANT SAFETY INFORMATION

WARNING: SEVERE TOXIC REACTIONS, INCLUDING EMBRYO-FETAL TOXICITY

Methotrexate can cause the following severe or fatal adverse reactions. Monitor closely and modify dose or discontinue methotrexate as appropriate.

- **Bone marrow suppression [see *Warnings and Precautions (5.1)*]**
- **Serious infections [see *Warnings and Precautions (5.2)*]**
- **Renal toxicity and increased toxicity with renal impairment [see *Warnings and Precautions (5.3)*]**
- **Gastrointestinal toxicity [see *Warnings and Precautions (5.4)*]**
- **Hepatic toxicity [see *Warnings and Precautions (5.5)*]**
- **Pulmonary toxicity [see *Warnings and Precautions (5.6)*]**
- **Hypersensitivity and dermatologic reactions [see *Warnings and Precautions (5.7)*]**
- **Methotrexate can cause embryo-fetal toxicity, including fetal death. Use in pJIA is contraindicated in pregnancy. Consider the benefits and risks of XATMEP and risks to the fetus when prescribing XATMEP to a pregnant patient with a neoplastic disease. Advise females and males of reproductive potential to use effective contraception during and after treatment with XATMEP [see *Contraindications (4)*, *Warnings and Precautions (5.9)*, *Use in Specific Populations (8.1, 8.3)*].**

***INDICATION**

Xatmep® (methotrexate) Oral Solution 2.5 mg/mL is a folate analog metabolic inhibitor indicated for the:

- treatment of pediatric patients with acute lymphoblastic leukemia (ALL) as part of a multi-phase, combination chemotherapy maintenance regimen.

ADDITIONAL IMPORTANT SAFETY INFORMATION

The recommended Xatmep dose is to be taken once weekly. Daily use has resulted in fatal toxicity.

Take Xatmep exactly as your doctor tells you.

An accurate dosing device should always be used. Ask your pharmacist for an accurate dosing device. A household teaspoon is not an accurate dosing device.

Xatmep includes a Boxed Warning for severe toxicity, including embryo-fetal toxicity and fetal death.

Xatmep Oral Solution should not be used if hypersensitive or allergic to methotrexate or any of the ingredients in Xatmep.

Xatmep Oral Solution should not be used when nursing.

Ask your doctor about the risks to the fetus if you or your partner is taking Xatmep (methotrexate) for the treatment of ALL.

Pregnancy should be avoided if either partner is taking Xatmep.

Contraception should be used by both females and males while either is taking Xatmep and for 6 months after the last dose taken by females and 3 months after last dose taken by males.

Methotrexate may affect the ability to have children. Methotrexate may affect menstrual cycles and sperm count.

Discuss vaccinations and immunizations with your doctor prior to receiving them, as they may not be as effective, or should be avoided during methotrexate therapy.

Xatmep may cause severe side effects, including organ toxicity. Organ toxicity may include: bone marrow, kidneys, gastrointestinal, liver, lung, skin, soft tissue and bone. Secondary malignancies may occur. Your doctor will monitor you for signs and symptoms of toxicity during treatment.

Other side effects of methotrexate include:

- mouth sores
- diarrhea
- vomiting
- abdominal distress
- fatigue
- chills
- fever
- dizziness
- decreased resistance to infection
- leukopenia (decrease in white blood cells)
- malaise

These are not all the possible side effects of Xatmep. **Your doctor or your patient's doctor is the best source of advice about side effects.**

Call your doctor immediately if you or your patient has any side effects that concern you or do not go away.

Tell your doctor about any other medications, including prescription and over-the-counter medications, supplements, vitamins, or herbal remedies you are taking.

Make sure to visit your doctor regularly.

Keep this and all medications out of the reach of children.

Ask your doctor or pharmacist about proper storage and disposal of dispensing bottles and dosing devices.

See full Prescribing Information for further information, including Boxed Warning.

You are encouraged to report NEGATIVE SIDE EFFECTS to Azurity Pharmaceuticals at 1-855-379-0383, or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.

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