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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
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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 Silvergate Pharmaceuticals at 1-855-379-0383, or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.

For more information, visit Xatmep.com or call 1-855-379-0382.

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Xatmep™
(methotrexate)
Oral Solution
2.5 mg/mL

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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.
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


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*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.
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- fatigue
- chills
- fever
- dizziness
- decreased resistance to infection
- leukopenia (decrease in white blood cells)
- malaise
- decreased organ function
- infection

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