Patient Information
XATMEP® (ZAT-mep)
(methotrexate)
oral solution

What is the most important information I should know about XATMEP?

XATMEP can cause serious side effects that may be severe and lead to death, including:

- **Decreased blood cell counts.** XATMEP 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. Your healthcare provider will do blood tests before you start XATMEP and at least monthly to check your blood cell counts. Call your healthcare provider right away if you develop any of the following:
  - a new fever
  - symptoms of infection
  - easy bruising or bleeding that will not stop (persistent bleeding)
- **Serious infections.** People who take XATMEP 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 XATMEP.
- **Kidney problems. Kidney problems, including sudden (acute) kidney failure can happen with XATMEP.**

  Your healthcare provider will do tests to check your kidney function before you start XATMEP and every 1 to 2 months during treatment. **Tell your healthcare provider right away** if you develop any signs or symptoms of kidney problems, including:
  - a big change (either increase or decrease) in the amount of urine you produce
  - swelling in your legs, ankles or feet
  - shortness of breath
  - tiredness
  - weight gain
- **Severe stomach and intestine (gastrointestinal) problems.**
  - Diarrhea, vomiting, nausea, and mouth sores can happen in people who take XATMEP.
  - **Inflammation of the intestine with severe bleeding and a tear in the intestinal wall (perforation) have happened with XATMEP and may 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 XATMEP.
  - Severe stomach and life-threatening intestinal problems can happen when XATMEP is taken with high doses of non-steroidal anti-inflammatory medicines (NSAIDs).

  Tell your healthcare provider if you develop diarrhea, vomiting, or mouth sores during treatment with XATMEP.

  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.** XATMEP can cause severe liver problems including liver scarring (fibrosis), cirrhosis, and liver failure that may not get better (possibly irreversible) and can cause death.
  - Your healthcare provider will do tests to check your liver function before you start XATMEP and every 1 to 2 months during treatment.
  - Liver function tests that stay abnormal over time may happen without any symptoms of liver problems but can be an early sign of liver fibrosis or cirrhosis.
  - The risk of liver problems increases if you have obesity, diabetes, high cholesterol, current or past liver disease, family history of liver disease, abnormal liver test results, or drink alcohol.

  Tell your healthcare provider if you get any signs or symptoms of liver problems during treatment with XATMEP, including:
  - tiredness
  - easy bleeding or bruising
  - loss of appetite
  - nausea
  - difficulty thinking clearly
  - swelling in your legs, feet or ankles
  - weight loss
  - itchy skin
  - yellowing of your skin or the white part of your eyes
  - weakness

- **Lung problems.** Lung problems can happen suddenly (acute) with XATMEP, or they can develop over a long period-of-time (chronic). Lung problems may not get better (possibly irreversible) and can cause death.
  - Your healthcare provider may do tests to check your lung function during treatment with XATMEP.
  - Tell your healthcare provider if you have any symptoms, including: cough (especially a dry cough), fever, or trouble breathing.
- **Severe allergic and skin reactions.** XATMEP can cause severe skin reactions that can lead to death.
  - XATMEP can cause reactivation of skin reactions that can happen after radiation therapy (radiation recall dermatitis)
  - **Tell your healthcare provider right away about any new or worsening skin rash during treatment with XATMEP.**
  - XATMEP can cause severe allergic reactions. **Do not** take XATMEP if you have had a severe allergic reaction to methotrexate in the past. **Get medical help right away** if you develop any of the following signs or symptoms of a severe allergic reaction during treatment with XATMEP:
    - skin rash, itching and hives
    - swelling of the face, lips, tongue, or throat
    - dizziness
    - trouble breathing
    - wheezing
    - fast heart rate
    - feeling faint
    - stomach-area pain
    - vomiting or diarrhea
- **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 XATMEP to see if you are pregnant.
  - **If you are being treated for a medical condition other than cancer, do not take XATMEP if you are pregnant. See "Who should not take XATMEP?"**
  - If you are taking XATMEP to treat your cancer**,** you and your healthcare provider will decide if you will take XATMEP if you are pregnant.
  - Use effective birth control (contraception) during treatment and for **6** months after your final dose of XATMEP. Ask your healthcare provider what forms of birth control you can use during this time.
  - **Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with XATMEP.**

  Males with female partners who are able to become pregnant:
  - Use effective birth control during treatment and for **3** months after your final dose of XATMEP.
  - **Tell your healthcare provider right away if your female partner becomes pregnant during treatment with XATMEP.**
- **Risk of death from taking XATMEP the wrong way. XATMEP is taken 1 time each week. Deaths have happened when methotrexate was taken every day instead of 1 time weekly. See "How should I take XATMEP?" for instructions on taking XATMEP correctly.** See "**What are the possible side effects of XATMEP"** for more information about side effects.

What is XATMEP?

XATMEP is a prescription medicine used:

- in combination with other chemotherapy medicines in children, for maintenance treatment of acute lymphoblastic leukemia (ALL)
- to treat children with active polyarticular juvenile idiopathic arthritis (pJIA) when their first treatment, including full dose non-steroidal anti-inflammatory medicines (NSAIDs) did not work well or they could not tolerate them.
- It is not known if XATMEP is safe in people with liver problems.

Do not take XATMEP if you:

- are pregnant and are not being treated for cancer. Pregnant women who do not have cancer should not take XATMEP. XATMEP 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 XATMEP?"**
- have or had a severe allergic reaction to methotrexate. See "**What is the most important information I should know about XATMEP?"** See the end of this leaflet for a complete list of ingredients in XATMEP.

Before taking XATMEP tell your healthcare provider about all of your medical conditions, including if you:

- have kidney problems or are receiving dialysis treatments
- have stomach ulcers (peptic ulcer disease)
- have ulcerative colitis

- have or have had liver problems, or a family history or liver problems
- drink alcohol-containing beverages. Tell your healthcare provider if there is any change in the amount of alcoholic beverages you drink during treatment with XATMEP.
- have diabetes
- have lung problems or fluid in your lungs (pleural effusion)
- have recently received or are scheduled to receive a vaccine. You should not receive live vaccines during treatment with XATMEP.
- have fluid in your stomach-area (ascites)
- have had or plan to have radiation treatment
- have low levels of folate (B vitamin)
- plan to have any surgery with general anesthesia, including dental surgery
- are breastfeeding or plan to breastfeed. XATMEP may pass into your breast milk. Do not breastfeed during treatment XATMEP.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Taking XATMEP 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 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 XATMEP?

- **Take XATMEP exactly as prescribed by your healthcare provider.**
- **Do not** take more XATMEP than prescribed. Do not change your dose of XATMEP unless your healthcare provider tells you to.
- **Take XATMEP by mouth 1 time each week (on the same day each week).**
  - **Do not take XATMEP every day. Severe side effects and death have happened in people who have mistakenly taken methotrexate every day instead of 1 time each week.**
  - **If you are not sure how often to take XATMEP, ask your healthcare provider or pharmacist.**
- Use an accurate dosing device that measures milliliters (mL) to take your prescribed dose of XATMEP.
  - **Do not** use a household teaspoon as it is not an accurate measuring device and can lead to overdose, which can cause serious side effects. Ask your pharmacist for a measuring device and for instructions for measuring the correct dose.
- If you are taking XATMEP for treatment of pJIA, your healthcare provider may have you take folate supplement to help reduce the chance of developing certain side effects, such as mouth sores.
- If you miss a dose of XATMEP, call your healthcare provider for instructions for when to take your next dose of XATMEP.
- If you take too much XATMEP, call your healthcare provider or go to the 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.

What should I avoid while taking XATMEP?

Avoid drinking alcohol during treatment with XATMEP.

What are the possible side effects of XATMEP?

XATMEP 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 XATMEP?"**
- **New (secondary) cancers.** New cancers can happen in people who take XATMEP. Certain blood cancers can happen during treatment with XATMEP. In some cases, these blood cancers may completely go away (regress completely) after XATMEP is stopped.
- **Possible fertility problems (infertility) in males and females.** XATMEP 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 XATMEP include:

- mouth sores
- low white blood cells. **See "What is the most important information I should know about XATMEP?"**
- nausea
- upset stomach
- increased liver function tests

Your healthcare provider may decrease your dose, temporarily stop, or completely stop treatment with XATMEP, if you develop certain side effects.

These are not all the side effects of XATMEP.

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 XATMEP?

- Store XATMEP in the refrigerator between 36°F to 46°F (2°C to 8°C) or at room temperature between 68°F to 77°F (20°C to 25°C).
- If XATMEP is stored at room temperature, throw it away (discard) after 60 days.
- XATMEP comes in a bottle with a child-resistant closure.
- Keep XATMEP bottle tightly closed in its original container.
- Avoid freezing and exposing XATMEP to excessive heat.

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

General information about the safe and effective use of XATMEP.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use XATMEP for a condition for which it was not prescribed. Do not give XATMEP to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about XATMEP that is written for healthcare professionals.

What are the ingredients in XATMEP?

Active Ingredient: methotrexate

Inactive Ingredients: purified water, sodium citrate, citric acid, methylparaben sodium, propylparaben sodium, sucralose, and sodium hydroxide or hydrochloric acid (pH adjuster).

Manufactured for: Azurity Pharmaceuticals, Inc. Woburn, MA

For additional information contact Azurity Pharmaceuticals at 1-800-461-7449.

This Patient Information has been approved by the U.S. Food and Drug Administration. Issued: 05/2026