

A photograph of a woman and a young child in a field of tall grass at sunset. The woman is sitting on a swing, and the child is standing next to her, kissing her on the cheek. The scene is bathed in the warm, golden light of the setting sun, with long shadows and a soft glow. The background shows a line of trees and a clear sky.

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 POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (pJIA).*

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 injections. 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 is 10 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 pJIA?

Polyarticular juvenile idiopathic arthritis (pJIA) is a chronic form of arthritis in children. “Polyarticular” means “affecting many joints.” “Idiopathic” means “from unknown causes.” And “chronic” means that the disease is “long-lasting.”

Like adults, children can get arthritis. The disease causes inflammation of the joints, pain, stiffness, swelling, and a loss of motion. pJIA is the most common type of arthritis in children and is characterized by affecting five or more joints within the first six months of having the disease.

What causes pJIA?

Most commonly, pJIA is caused by an autoimmune disorder. Scientists don’t know why this happens, but sometimes a person’s immune system attacks the body’s healthy cells and tissues instead of helping to fight off harmful bacteria and viruses. One of the results may be the development of pJIA.

What are symptoms and signs of pJIA?

The symptoms of pJIA that are most common include constant joint swelling, pain, and stiffness. A child’s knees, hands, and feet are most often affected, and symptoms are often worse in the morning or after a nap. Other signs you might observe include:

- Limping, especially in the morning
- Extreme clumsiness
- A high fever or a skin rash
- Swelling of lymph nodes in a child’s neck or other parts of the body

Most children with pJIA experience times when symptoms get better or go away (called “remission”), and other times when symptoms get worse (called a “flare”).

How is pJIA diagnosed?

Doctors often think of arthritis when they see a child with constant joint pain or swelling. Other symptoms may include unexplained skin rashes, or fevers that accompany swelling of lymph nodes or inflammation of a child’s organs. To confirm diagnosis, a doctor may do any or all of the following:

- Perform a thorough physical exam
- Take note of all symptoms
- Check a family’s history of related diseases
- Perform laboratory tests
- Take x-rays of affected joints

How is pJIA treated?

To treat pJIA, doctors often prescribe methotrexate [now available as Xatmep™ (methotrexate) Oral Solution 2.5 mg/mL, a ready-to-use oral liquid], when non-steroidal anti-inflammatory drugs (NSAIDs, like aspirin, ibuprofen, or naproxen) are not enough. Researchers have learned that methotrexate is safe and effective for some children with pJIA.

How can you help your child live with pJIA?

pJIA is a disease that affects the entire family. Plus, it can restrict a child's social and after-school activities and even make schoolwork more difficult. To help a child with pJIA, both physically and emotionally, consider:

- Getting the best care available
- Learning as much you can about pJIA and its treatment
- Joining a support group
- Treating your child as normally as possible
- Encouraging exercise and physical therapy for your child
- Working closely with your child's school
- Talking with, and listening to, your child
- Working with therapists or social workers who can help

Source: Juvenile Arthritis. National Institutes of Health: National Institute of Arthritis and Musculoskeletal and Skin Diseases. www.niams.nih.gov/health-topics/juvenile-arthritis. 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:

- management of pediatric patients with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs).

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 during pregnancy in patients with pJIA or when nursing.

Use of Xatmep (methotrexate) in pJIA is contraindicated in pregnancy.

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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