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## Methotrexate: Patient drug information

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(For additional information <u>see "Methotrexate: Drug information"</u> and <u>see "Methotrexate: Pediatric drug information"</u>)

**Brand Names: US** Otrexup; Rasuvo; Rheumatrex [DSC]; Trexall; Xatmep

**Brand Names: Canada** Apo-Methotrexate; JAMP-Methotrexate; Methotrexate Injection USP; Methotrexate Injection, BP; Methotrexate Sodium Injection; Metoject; ratio-Methotrexate Sodium

## Warning

### For all uses of this drug:

- Very bad side effects like bone marrow problems, liver problems, lung problems, infections, and skin reactions (Stevens-Johnson syndrome/toxic epidermal necrolysis) can happen with this drug. Some side effects may not go away and can be deadly. You must talk with the doctor about the risks of this drug.
- This drug may cause kidney problems in some patients. Talk with the doctor.
- Regular blood work and other exams will need to be done to check for side effects. Follow what the
  doctor has told you.
- Tell your doctor if you have kidney problems or extra fluid around your stomach area or lungs. The chance of side effects may be raised.
- Very bad and sometimes deadly bone marrow problems and stomach or bowel problems have happened when this drug was taken with NSAIDs like ibuprofen or naproxen. Talk with the doctor.
- This drug may raise your chance of lymphoma and other cancers.
- Patients with cancer may be at greater risk of getting a bad and sometimes deadly health problem called tumor lysis syndrome (TLS). Talk with the doctor.
- Tell your doctor if you get loose stools (diarrhea) or mouth or tongue sores or irritation. You may need to stop this drug. Very bad and sometimes deadly bowel problems may happen.
- Talk with your doctor if you are getting radiation. There may be more chance of harm to tissue and bone.
- · Not all methotrexate products are used to treat cancer. Talk with the doctor.
- This drug may cause harm to the unborn baby or loss of the unborn baby if you take it while you are pregnant.
- If you are pregnant or you get pregnant while taking this drug, call your doctor right away.

### Psoriasis or rheumatoid arthritis:

- · Do not take if you are pregnant.
- This drug must only be used when other drugs cannot be used or have not worked. Talk with your doctor to be sure that the benefits of this drug are more than the risks.

## What is this drug used for?

- · It is used to treat cancer.
- · It is used to treat rheumatoid arthritis.
- · It is used to treat juvenile arthritis.
- · It is used to treat psoriasis.
- It may be given to you for other reasons. Talk with the doctor.

## What do I need to tell my doctor BEFORE I take this drug?

- · If you have an allergy to methotrexate or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your
  doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath;
  wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- If you have any of these health problems: Bone marrow disease (like low white blood cell count, low platelet count, or anemia), drinking problem, liver disease, or a weak immune system.
- If you are breast-feeding. Do not breast-feed while you take this drug.
  - This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

# What are some things I need to know or do while I take this drug?

#### All products:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- Talk with your doctor before getting any vaccines. Use with this drug may either raise the chance of an infection or make the vaccine not work as well.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
- · Avoid drinking alcohol while taking this drug.
- You may get sunburned more easily. Avoid sun, sunlamps, and tanning beds. Use sunscreen and
  wear clothing and eyewear that protects you from the sun. Keep protecting yourself from sunburn for
  as long as you were told by your doctor.

- Tell your doctor if you have too much sweat, fluid loss, throwing up, loose stools (diarrhea), not hungry, or more thirst.
- Patients with cancer who take this drug may be at greater risk of getting a bad and sometimes deadly
  health problem called tumor lysis syndrome (TLS). Call your doctor right away if you have a fast
  heartbeat or a heartbeat that does not feel normal; any passing out; trouble passing urine; muscle
  weakness or cramps; upset stomach, throwing up, loose stools or not able to eat; or feel sluggish.
- A very bad skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause very bad health problems that may not go away, and sometimes death. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in your mouth, throat, nose, or eyes.
- If you are 65 or older, use this drug with care. You could have more side effects.
- This drug may affect fertility. Fertility problems may lead to not being able to get pregnant or father a child. Talk with the doctor.
- If you are a man and have sex with a female who could get pregnant, protect her from pregnancy during care and for 3 months after care ends. Use birth control that you can trust.
- A pregnancy test will be done to show that you are NOT pregnant before starting this drug. If you get pregnant while taking this drug, call your doctor right away.
- Use birth control that you can trust to prevent pregnancy during care and for some time after care ends. Talk with your doctor to see how long to use birth control after you stop this drug.
- If you are a woman and you miss a period, have unprotected sex, or think that your birth control has not worked, call your doctor right away.

#### **Injection:**

• Some products have benzyl alcohol. Do not give a product that has benzyl alcohol in it to a newborn. Talk with the doctor to see if this product has benzyl alcohol in it.

## What are some side effects that I need to call my doctor about right away?

**WARNING/CAUTION:** Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of bleeding like throwing up blood or throw up that looks like coffee grounds; coughing up blood; blood in the urine; black, red, or tarry stools; bleeding from the gums; vaginal bleeding that is not normal; bruises without a reason or that get bigger; or any bleeding that is very bad or that you cannot stop.
- Signs of a pancreas problem (pancreatitis) like very bad stomach pain, very bad back pain, or very bad upset stomach or throwing up.
- Signs of kidney problems like unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain.
- Signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- · Signs of lung or breathing problems like shortness of breath or other trouble breathing, cough, or

fever.

- · Pinpoint red spots on the skin.
- · Very bad dizziness or passing out.
- · Seizures.
- · Feeling confused.
- · Change in eyesight.
- · Bone pain.
- Swelling, warmth, numbness, change of color, or pain in a leg or arm.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- · Headache.
- · Neck stiffness.
- · Not able to move.

## What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- · Upset stomach.
- · Hair loss.
- · Feeling tired or weak.
- · Dizziness.
- · Belly pain.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

# How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

#### **All products:**

- Drink lots of noncaffeine liquids unless told to drink less liquid by your doctor.
- Take as you have been told by your doctor. This drug is not to be used every day. Be sure you know how to use this drug.
- To gain the most benefit, do not miss doses.
- How this drug is taken may change based on blood work results, side effects, and how well the drug is working.
- Do not switch between different forms of this drug without first talking with the doctor.
- You will need to take special care when handling this drug. Check with the doctor or pharmacist to see how to handle this drug.

#### <u>Liquid (solution):</u>

• Measure liquid doses carefully. Use the measuring device that comes with this drug. If there is none, ask the pharmacist for a device to measure this drug.

### <u>Injection (subcutaneous):</u>

- It is given as a shot into the fatty part of the skin on the top of the thigh or the belly area.
- If you will be giving yourself the shot, your doctor or nurse will teach you how to give the shot.
- Follow how to use as you have been told by the doctor or read the package insert.
- Do not use if the solution is cloudy, leaking, or has particles.
- · Do not give into red or irritated skin.
- Throw away needles in a needle/sharp disposal box. Do not reuse needles or other items. When the
  box is full, follow all local rules for getting rid of it. Talk with a doctor or pharmacist if you have any
  questions.

## Injection (I.M., I.V.):

- · It is given as a shot into a muscle or vein.
- · A shot may be given into the spinal fluid.
- This drug will be given to you by a doctor.

## What do I do if I miss a dose?

· Call your doctor to find out what to do.

## How do I store and/or throw out this drug?

### <u>Tablets and injection (subcutaneous):</u>

- Store at room temperature. Do not freeze.
- Store in a dry place. Do not store in a bathroom.
- · Protect from light.

### **Liquid (solution):**

- Store solution in a refrigerator or at room temperature. Throw away any unused portion after 2 months.
- · Do not freeze.

## Injection (I.M., I.V.):

• If you need to store this drug at home, talk with your doctor, nurse, or pharmacist about how to store it.

#### All products:

- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Check with your pharmacist about how to throw out unused drugs.

## **General drug facts**

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.

- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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