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Methotrexate: Patient drug information Lexicomp*

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(For additional information see "Methotrexate: Drug information" and see "Methotrexate: Pediatric drug information")

You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Brand Names: US

Otrexup; Rasuvo; RediTrex; Trexall; Xatmep

Brand Names: Canada

JAMP-Methotrexate; Metoject; PMS-Methotrexate; RATIO-Methotrexate Sodium [DSC]

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.

- Talk with your doctor if you are getting radiation. There may be more chance of harm to tissue and bone.
- New types of cancer have happened in people taking this drug. If you have questions, talk with the doctor.
- It is common to have diarrhea, upset stomach, throwing up, or mouth sores with this drug. However, sometimes these may be signs of severe and sometimes deadly stomach or bowel problems. Tell your doctor if you get any new or worsening signs. You may need to stop this drug.
- Very bad and sometimes deadly bone marrow problems and stomach or bowel problems have happened when this drug was taken with nonsteroidal anti-inflammatory drug (NSAIDs) like ibuprofen or naproxen.
- Not all methotrexate products are used to treat cancer. Talk with the doctor.
- This drug may cause harm to an unborn baby or loss of an unborn baby. A pregnancy test will be done before you start this drug to show that you are NOT pregnant.
- If you may become pregnant, you must use birth control while taking this drug and for some time after the last dose. Ask your doctor how long to use birth control. If you get pregnant, call your doctor right away.
- If your sex partner may get pregnant, you must use birth control while taking this drug and for some time after the last dose. Ask your doctor how long to use birth control. If your partner gets pregnant, call the doctor right away.

Cancer treatment:

• 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.

For all reasons other than cancer treatment:

- 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.

Injection:

 Some products have benzyl alcohol. These products must not be given to a newborn or infant. These products may also not be right for some other people. Talk with the doctor to see if this product has benzyl alcohol in it.

What is this drug used for?

- It is used to treat cancer.
- It is used to treat some types of arthritis.
- It is used to treat some types of 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?

<u>All products:</u>

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- 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. You may also need to avoid breast-feeding for some time after your last dose. Talk with your doctor to see if you need to avoid breast-feeding after your last dose.

<u>Tablets:</u>

• If you are not able to swallow tablets.

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?

For all uses of this drug:

- 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.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- Call your doctor right away if you have any signs of infection like fever, chills, flulike signs, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or a wound that will not heal.
- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
- Call your doctor right away if you have any signs of bleeding problems, like bruising; black, tarry, or bloody stools; bleeding gums; blood in the urine; coughing up blood; cuts that take a long time to stop bleeding; feel dizzy; feeling very tired or weak; nosebleeds; pain or swelling; throwing up blood or throw up that looks like coffee grounds; or very bad headache.
- Talk with your doctor before getting any vaccines. Use of some vaccines with this drug may either raise the chance of an infection or make the vaccine not work as well.
- Talk with your doctor before you drink alcohol.
- 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, diarrhea, not hungry, or more thirst.

- Nervous system problems that may be severe have happened with this drug.
 Some lasted for a short time while some lasted for a long time. These nervous system problems can get worse over time, may not get better, and can be deadly.
 If you have questions, talk with the doctor.
- If you are 65 or older, use this drug with care. You could have more side effects.
- This drug may affect fertility. This may lead to not being able to get pregnant or father a child. If this happens, it is not known if fertility will go back to normal.
- 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.

<u>Cancer treatment:</u>

• If you are taking a product that has folic acid or folinic acid in it, talk with your doctor. It may make this drug not work as well.

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:

For all uses of this drug:

- 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, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- 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.
- Signs of nerve problems like a burning, numbness, or tingling feeling that is not normal; weakness; or not being able to move a part of the body (paralysis).
- Signs of a severe skin reaction (Stevens-Johnson syndrome) like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in the mouth, throat, nose, or eyes.
- Pinpoint red spots on the skin.
- Very bad dizziness or passing out.
- Seizures.
- Feeling confused.
- Feeling sleepy.
- 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.

<u>Cancer treatment:</u>

• Signs of a severe health problem called tumor lysis syndrome (TLS) like fast or abnormal heartbeat; passing out; trouble passing urine; muscle weakness or cramps; upset stomach, throwing up, diarrhea, or not able to eat; or feeling sluggish.

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:

- Not hungry.
- Hair loss.
- Feeling dizzy, tired, or weak.
- Stomach pain.
- Signs of a common cold.

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.

<u>All products:</u>

- Your dose and how often you take it will be based on the health problem that is being treated. This drug must **NEVER** be taken daily unless used for some types of cancer. Deadly errors have happened when this drug was taken the wrong way. Be sure you know how to take this drug. If you do not understand what your dose is and how often to take it, talk with your doctor.
- How this drug is taken may change based on blood work results, side effects, and how well the drug is working.
- You will need to take special care when handling this drug. Check with the doctor or pharmacist to see how to handle this drug.
- Drink lots of noncaffeine liquids unless told to drink less liquid by your doctor.
 <u>Oral 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.

• Do not use a household teaspoon or tablespoon to measure this drug. Doing so could lead to the dose being too high.

Injection (subcutaneous):

- 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.
- Do not give into skin within 2 inches of the belly button.
- Do not use if the solution is cloudy, leaking, or has particles.
- Do not give into skin that is irritated, tender, bruised, red, scaly, hard, scarred, or has stretch marks.
- If you are not sure if your dose was injected or if you have a hard time giving the dose, talk with your doctor or pharmacist before using another dose.
- 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.

All other injection products:

- It is given as a shot into a muscle or vein.
- A shot may be given into the spinal fluid.

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?

Oral solution:

• Store liquid (solution) in a refrigerator or at room temperature. If stored at room

temperature, throw away any part not used after 2 months.

- Keep lid tightly closed.
- Do not freeze.
- Protect from heat.

Tablets and injection (subcutaneous):

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

All other injection products:

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

<u>All products:</u>

- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

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.
- 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.

Last Reviewed Date

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Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information is governed by the Lexicomp End User License Agreement, available at https://www.wolterskluwer.com/en/solutions/lexicomp/about/eula.

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