



Methotrexate

(meth" oh trex' ate)

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IMPORTANT WARNING:

Methotrexate may cause very serious side effects. Some side effects of methotrexate may cause death. You should only take methotrexate to treat life-threatening cancer, or certain other conditions that are very severe and that cannot be treated with other medications. Talk to your doctor about the risks of taking methotrexate for your condition.

Tell your doctor if you have or have ever had excess fluid in your stomach area or in the space around your lungs and if you have or have ever had kidney disease. Also tell your doctor if you are taking nonsteroidal anti-inflammatory drugs (NSAID) such as aspirin, choline magnesium trisalicylate (Tricosal, Trilisate), ibuprofen (Advil, Motrin), magnesium salicylate (Doan's), naproxen (Aleve, Naprosyn), or salsalate. These conditions and medications may increase the risk that you will develop serious side effects of methotrexate. Your doctor will monitor you more carefully and may need to give you a lower dose of methotrexate or stop your treatment with methotrexate.

Methotrexate may cause a decrease in the number of blood cells made by your bone marrow. Tell your doctor if you have or have ever had a low number of any type of blood cells or any other problem with your blood cells. Your doctor may tell you not to take methotrexate unless you have life-threatening cancer. Call your doctor immediately if you experience any of the following symptoms: sore throat, chills, fever, or other signs of infection; unusual bruising or bleeding; excessive tiredness; pale skin; or shortness of breath.

Methotrexate may cause liver damage, especially when it is taken for a long period of time. If you drink or have ever drunk large amounts of alcohol or if you have or have ever had liver disease, your doctor may tell you not to take methotrexate unless you have a life-threatening form of cancer because there is a higher risk that you will develop liver damage. The risk that you will develop liver damage may also be higher if you are elderly, obese, or have diabetes. Tell your doctor if you are taking any of the following medications: acitretin (Soriatane), azathioprine (Imuran), isotretinoin (Accutane), sulfasalazine (Azulfidine), or tretinoin (Vesanoïd). To decrease the risk of developing liver damage, do not drink alcohol while you are taking methotrexate. Call your doctor immediately if you experience any of the following symptoms: nausea, extreme tiredness, lack of energy, loss of appetite, pain in the upper right part of the stomach, yellowing of the skin or eyes, or flu-like symptoms. Your doctor may order liver biopsies (removal of

a small piece of liver tissue to be examined in a laboratory) before and during your treatment with methotrexate.

Methotrexate may cause lung damage. Tell your doctor if you have or have ever had lung disease. Call your doctor immediately if you experience any of the following symptoms: dry cough, fever, or shortness of breath.

Methotrexate may cause damage to the lining of your mouth, stomach or intestines. Tell your doctor if you have or have ever had stomach ulcers or ulcerative colitis (condition in which part or all of the lining of the intestine is swollen or worn away). If you experience any of the following symptoms, stop taking methotrexate and call your doctor right away: mouth sores, diarrhea, black, tarry, or bloody stools, or vomit that is bloody or looks like coffee grounds.

Taking methotrexate may increase the risk that you will develop lymphoma (cancer that begins in the cells of the immune system). If you do develop lymphoma, it might go away without treatment when you stop taking methotrexate, or it might need to be treated with chemotherapy.

If you are taking methotrexate to treat cancer, you may develop certain complications as methotrexate works to destroy the cancer cells. Your doctor will monitor you carefully and treat these complications if they occur.

Methotrexate may cause serious or life-threatening skin reactions. If you experience any of the following symptoms, call your doctor immediately: fever, rash, blisters, or peeling skin.

Methotrexate may decrease the activity of your immune system, and you may develop serious infections. Tell your doctor if you have any type of infection and if you have or have ever had any condition that affects your immune system. Your doctor may tell you that you should not take methotrexate unless you have life-threatening cancer. If you experience signs of infection such as a sore throat, cough, fever, or chills, call your doctor immediately.

If you take methotrexate while you are being treated with radiation therapy for cancer, methotrexate may increase the risk that the radiation therapy will cause damage to your skin, bones, or other parts of your body.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests before, during, and after your treatment to check your body's response to methotrexate and to treat side effects before they become severe.

Tell your doctor if you or your partner is pregnant or plan to become pregnant. If you are female, you will need to take a pregnancy test before you begin taking methotrexate. Use a reliable method of birth control so that you or your partner will not become pregnant during or shortly after your treatment. If you are male, you and your female partner should continue to use birth control for 3 months after you stop taking methotrexate. If you are female, you should continue to use birth control until you have had one menstrual period that began after you stopped taking methotrexate. If you or your partner become pregnant, call your doctor immediately. Methotrexate may harm the fetus.

Why is this medication prescribed?

Methotrexate is used to treat severe psoriasis (a skin disease in which red, scaly patches form on some areas of the body) that cannot be controlled by other treatments. Methotrexate is also used along with rest, physical therapy and sometimes other medications to treat severe active rheumatoid arthritis (RA; a condition in which the body attacks its own joints, causing pain, swelling, and loss of function) that cannot be controlled by certain other medications. Methotrexate is also used to treat certain types of cancer including cancers that begin in the tissues that form around a fertilized egg in the uterus, breast cancer, lung cancer, certain cancers of the head and neck, certain types of lymphoma, and leukemia (cancer that begins in the white blood cells). Methotrexate is in a class of medications called antimetabolites. Methotrexate treats cancer by slowing the growth of cancer cells. Methotrexate treats psoriasis by slowing the growth of skin cells to stop scales from forming. Methotrexate may treat rheumatoid arthritis by decreasing the activity of the immune system.

How should this medicine be used?

Methotrexate comes as a tablet to take by mouth. Your doctor will tell you how often you should take methotrexate. The schedule depends on the condition you have and on how your body responds to the medication.

Your doctor may tell you to take methotrexate on a rotating schedule that alternates several days when you take methotrexate with several days or weeks when you do not take the medication. Follow these directions carefully and ask your doctor or pharmacist if you do not know when to take your medication.

If you are taking methotrexate to treat psoriasis or rheumatoid arthritis, your doctor may tell you to take the medication once a week. Pay close attention to your doctor's directions. Some people who mistakenly took methotrexate once daily instead of once weekly experienced very severe side effects or died.

Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take methotrexate exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

If you are taking methotrexate to treat psoriasis or rheumatoid arthritis, your doctor may start you on a low dose of the medication and gradually increase your dose. Follow these directions carefully.

If you are taking methotrexate to treat rheumatoid arthritis, it may take 3 to 6 weeks for your symptoms to begin to improve, and 12 weeks or longer for you to feel the full benefit of methotrexate. Continue to take methotrexate even if you feel well. Do not stop taking methotrexate without talking to your doctor.

Other uses for this medicine

Methotrexate is also sometimes used to treat Crohn's disease (condition in which the immune system attacks the lining of the digestive tract, causing pain, diarrhea, weight loss and fever), multiple sclerosis (MS; condition in which the immune system attacks the nerves, causing weakness, numbness, loss of muscle coordination, and problems with vision, speech, and bladder control), and other conditions that develop when the immune system is over-active. Ask your doctor about the risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking methotrexate,

- tell your doctor and pharmacist if you are allergic to methotrexate, any other medications, or any of the ingredients in methotrexate tablets. Ask your doctor or pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following: certain antibiotics such as chloramphenicol (chloramycetin), penicillins, and tetracyclines; folic acid (available alone or as an ingredient in some multivitamins); other medications for rheumatoid arthritis; phenytoin (Dilantin); probenecid (Benemid); sulfonamides such as co-trimoxazole (Bactrim, Septra), sulfadiazine, sulfamethizole (Urobiotic), and sulfisoxazole (Gantrisin); and theophylline (Theochron, Theolair). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had any of the conditions mentioned in the IMPORTANT WARNING section or a low level of folate in your blood.
- do not breast-feed while you are taking methotrexate.

- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking methotrexate.
- plan to avoid unnecessary or prolonged exposure to sunlight or ultraviolet light (tanning beds and sunlamps) and to wear protective clothing, sunglasses, and sunscreen. Methotrexate may make your skin sensitive to sunlight or ultraviolet light. If you have psoriasis, your sores may get worse if you expose your skin to sunlight while you are taking methotrexate.
- do not have any vaccinations during your treatment with methotrexate without talking to your doctor.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Methotrexate may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- dizziness
- drowsiness
- headache
- swollen, tender gums
- decreased appetite
- reddened eyes
- hair loss

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- blurred vision or sudden loss of vision
- seizures
- confusion
- weakness or difficulty moving one or both sides of the body
- loss of consciousness

Methotrexate may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/MedWatch/index.html>] or by phone [1-800-332-1088].

What storage conditions are needed for this medicine?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

What other information should I know?

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Rheumatrex®
- Trexall®

Other names

- Amethopterin
- MTX

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