

Patient Education for METHOTREXATE 2.5 MG TABLET



Call doctor if symptoms of GI bleeding If available, dispense patient package insert and explain to pt Report signs of liver trouble to doctor promptly (jaundice etc) May cause drowsiness or dizziness Use caution driving. Avoid alcohol and NSAIDs. Low dose aspirin ok if ordered by MD. Call MD if irregular pulse, sores, growths, bleeding, or infections. May suppress immune system. Avoid infections/newly immunized people. Teratogenic-Avoid getting pregnant or use while pregnant or nursing.

Call Dr if you have black stools or stomach pain If available, read the patient package insert Call MD if new abdominal pain/yellowing eyes/skin May make you drowsy or dizzy. Drive with caution No alcohol/aspirin-like meds. Ask MD re: aspirin. Call MD immediately for changes in your condition Avoid infections and recently immunized people Avoid getting pregnant or use when pregnant/nursing

.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

METHOTREXATE - ORAL
(METH-oh-TREX-ate)

COMMON BRAND NAME(S):

Rheumatrex, Trexall, Xatmep

WARNING:

Methotrexate has rarely caused serious (sometimes fatal) side effects. This medication should be used only to treat cancer or severe diseases caused by an overactive immune system (such as psoriasis, rheumatoid arthritis).

Methotrexate has caused birth defects and death in unborn babies. Women must avoid becoming pregnant while taking this medication. Pregnant women who have psoriasis or rheumatoid arthritis must not use methotrexate. (See also Precautions section.)

If you have kidney problems or excess body water (ascites, pleural effusion), you must be closely monitored and your dose may be adjusted or stopped by your doctor.

Methotrexate (usually at high dosages) has rarely caused severe (sometimes fatal) blood/bone marrow problems (decreasing your body's ability to fight infections) and stomach/intestinal disease (such as bleeding) when used at the same time as non-steroidal anti-inflammatory drugs (NSAIDs such as indomethacin, ketoprofen). NSAIDs should not be used with high-dose methotrexate. Caution is advised if you also take aspirin. NSAIDs/aspirin may be used with low-dose methotrexate such as for the treatment of rheumatoid arthritis if directed by your doctor. If your doctor has directed you to take low-dose aspirin for heart attack or stroke prevention (usually at dosages

of 81-325 milligrams a day), you should continue taking it unless your doctor instructs you otherwise. Ask your doctor or pharmacist for more details on the safe use of these drugs (such as close monitoring by your doctor, keeping the same doses of NSAIDs).

In rare instances, this drug may also cause liver problems when it is used for long periods of time. If you are using methotrexate long term, a liver biopsy is usually recommended.

Methotrexate use has rarely caused serious (sometimes fatal) side effects, such as lung problems, lung infections (Pneumocystis jiroveci pneumonia), skin reactions, diarrhea, and mouth sores (ulcerative stomatitis). (See also Side Effects section.)

Lumps (tumors/abnormal growths) may very rarely appear during methotrexate use. The drug must be stopped and treatment may be needed. Tell your doctor right away if new lumps/growths occur.

When used to treat tumors, methotrexate sometimes causes side effects due to the rapid destruction of cancer cells (tumor lysis syndrome). To lower your risk, drink plenty of fluids unless your doctor directs you otherwise. Also, your doctor may prescribe an additional medication. Tell your doctor right away if you have symptoms such as irregular heartbeat, low back/side pain, signs of kidney problems (such as pink/bloody urine, change in the amount of urine, painful urination), or muscle spasms/weakness.

When this medication is used with radiation treatment, it may rarely increase the risk of tissue and bone damage. Discuss the risks and benefits of your treatment with your doctor.

USES:

Methotrexate is used to treat certain types of cancer (such as acute lymphoblastic leukemia, non-Hodgkin's lymphoma) or to control severe psoriasis or rheumatoid arthritis that has not responded to other treatments. It may also be used to control juvenile rheumatoid arthritis. Methotrexate belongs to a class of drugs known as antimetabolites. It works by slowing or stopping the growth of cancer cells and suppressing the immune system.

Early treatment of rheumatoid arthritis with more aggressive therapy such as methotrexate helps to reduce further joint damage and to preserve joint function.

OTHER USES:

This section contains uses of this drug that are not

listed in the approved professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional.

This medication may also be used for lupus and psoriatic arthritis.

HOW TO USE:

Read the Patient Information Leaflet if available

from your pharmacist before you start taking methotrexate and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

Methotrexate is a strong medication. The dosage and how often you take this medication are based on your medical condition and response to treatment. There are many different dosing schedules for this medication (especially for cancer treatment). Taking this medication the wrong way may cause serious side effects, including death. It is very important that you follow your doctor's instructions carefully. Take this medication by mouth as directed by your doctor.

For the treatment of psoriasis or rheumatoid arthritis, take this medication by mouth as directed by your doctor, usually once a week. It may take up to several months before you get the full benefit of this drug.

If you are using the liquid form of this medication, carefully measure the dose using a special measuring device/spoon. Do not use a household spoon because you may not get the correct dose.

Do not increase your dose or use this drug more often or for longer than prescribed. Your condition will not improve any faster, and your risk of side effects will increase.

Since this drug can be absorbed through the skin and lungs and may harm an unborn baby, women who are pregnant or who may become pregnant should not handle this medication or breathe the dust from the tablets.

Drink plenty of fluids while taking this medication unless your doctor tells you otherwise. Doing so helps your kidneys to remove the drug from your body and avoid some of the side effects.

SIDE EFFECTS:

See also Warning section.

Nausea, vomiting, stomach pain, drowsiness, or dizziness may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly.

Temporary hair loss may occur. Normal hair growth should return after treatment has ended.

Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if you have any serious side effects, including: mouth sores, diarrhea, signs of anemia (such as unusual tiredness, pale skin), signs of liver problems (such as nausea/vomiting that doesn't stop, dark urine, stomach/abdominal pain, yellowing eyes/skin), easy bruising/bleeding, black stools, enlarged glands/lymph nodes, bone pain, unusual pain and discoloration of the skin, signs of

kidney problems (such as change in the amount of urine), dry cough, muscle weakness.

Get medical help right away if you have any very serious side effects, including: weakness on one side of the body, neck stiffness, severe headache, vision changes, irregular heartbeat, mental/mood changes, seizures.

This medication may lower your ability to fight infections. This may make you more likely to get a serious (rarely fatal) infection or make any infection you have worse. Tell your doctor right away if you have any signs of infection (such as sore throat that doesn't go away, fever, chills, cough).

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:

See also Warning section.

Before taking methotrexate, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, kidney disease, lung disease (such as pulmonary fibrosis), alcohol use, suppressed immune system, blood cell/bone marrow disorders, stomach/intestinal diseases (such as peptic ulcer, ulcerative colitis), any active infection (including chickenpox or recent exposure to it), folic acid deficiency.

Methotrexate can make you more likely to get infections or may worsen any current infections. Avoid contact with people who have infections that may spread to others (such as chickenpox, measles, flu). Consult your doctor if you have been exposed to an infection or for more details.

Tell your health care professional that you are using methotrexate before having any immunizations/vaccinations. Avoid contact with people who have recently received live vaccines (such as flu vaccine inhaled through the nose).

To lower the chance of getting cut, bruised, or injured, use caution with sharp objects like razors and nail cutters, and avoid activities such as contact sports.

This drug may make you dizzy or drowsy. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Avoid alcoholic beverages. Talk to your doctor if you

are using marijuana (cannabis).

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

This medication may make you more sensitive to the sun. Limit your time in the sun. Avoid tanning booths and sunlamps. Use sunscreen and wear protective clothing when outdoors. Tell your doctor right away if you get sunburned or have skin blisters/redness.

This medication can affect fertility in both males and females. Ask your doctor for more details.

Methotrexate must not be used during pregnancy. It may harm an unborn baby. Your doctor should do a pregnancy test before you start this medication. You should not become pregnant while using methotrexate. Women of childbearing age should ask about reliable forms of birth control while using this medication and for 6 months after the last dose. Men with female partners of childbearing age should ask about reliable forms of birth control while using this medication and for 3 months after the last dose. If you or your partner become pregnant, or think you are pregnant, talk to your doctor right away about the risks and benefits of this medication

Since this drug can be absorbed through the skin and lungs and may harm an unborn baby, women who are pregnant or who may become pregnant should not handle this medication or breathe the dust from the tablets.

Methotrexate passes into breast milk and may harm a nursing infant. Breast-feeding is not recommended while using this drug and for at least 1 week after the end of treatment. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

See also Warning section.

Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: acitretin, asparaginase, chloramphenicol, leflunomide, other drugs that can cause kidney problems (such as cisplatin), other drugs that can cause liver problems (such as azathioprine, sulfasalazine, retinoids such as isotretinoin), penicillins, phenytoin, probenecid, procarbazine, pyrimethamine, sulfa medications, tetracyclines.

Certain drugs that reduce stomach acid (proton pump inhibitors-PPIs such as esomeprazole, omeprazole, pantoprazole) may increase the amount of methotrexate in your blood. This effect may increase the risk of side effects, especially with high-dose methotrexate treatment. Ask your doctor or pharmacist for details and ways to lessen the risk of side effects.

OVERDOSE:

If someone has overdosed and has serious symptoms such

as passing out or trouble breathing, call 911. Otherwise, call a

poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include severe nausea and vomiting, and bloody stools.

NOTES:

Do not share this medication with others.

Laboratory and/or medical tests (such as complete blood cell counts, liver and kidney function tests, pregnancy test, chest X-ray) should be performed before you start treatment, periodically to monitor your progress, or to check for side effects. Consult your doctor for more details.

MISSED DOSE:

It is important to take each dose of this

medication as scheduled. If you miss a dose, ask your doctor or pharmacist right away for a new dosing schedule. Do not double the dose to catch up.

STORAGE:

Store the tablets at room temperature away from light

and moisture. Do not store in the bathroom. Keep all medications away from children and pets.

Store the liquid form in the refrigerator or at room temperature. If stored at room temperature, discard after 60 days.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

MEDICAL ALERT:

Your condition can cause complications in a

medical emergency. For information about enrolling in MedicAlert, call 1-888-633-4298 (US) or 1-800-668-1507 (Canada).

Information last revised March 2022.

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