



Patient Information Methotrexate Tablets, USP (meth' oh trex' ate)
Read the Patient Instructions that come with methotrexate tablets before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition.
<p>What is the most important information I should know about methotrexate tablets?</p> <ul style="list-style-type: none"> • Methotrexate tablets can cause serious side effects that may be life threatening (see “What are the possible or reasonably likely side effects of methotrexate?”). Most side effects can be found by medical tests before they become serious. Your doctor may do regular tests to check how methotrexate tablets are affecting your body. It is important that you stay under a doctor’s care while taking methotrexate tablets. Call your doctor right away to report any side effects or symptoms you get. • Methotrexate tablets can cause birth defects or death of an unborn child. Therefore, if you are pregnant or your sexual partner is pregnant, or plans to become pregnant, do not take methotrexate tablets. Neither you nor your partner should become pregnant while taking methotrexate tablets. Women should wait at least 1 menstrual cycle after stopping treatment with methotrexate tablets before getting pregnant. Men should wait at least 3 months after stopping treatment with methotrexate tablets before getting their partner pregnant. Women who can become pregnant should have a pregnancy test before starting methotrexate. During treatment with methotrexate tablets men whose partners and women who are able to get pregnant should use effective birth control.
<p>What is methotrexate?</p> <p>Methotrexate is a prescription medicine used in treating certain cancers, severe rheumatoid arthritis including polyarticular juvenile rheumatoid arthritis, and severe psoriasis.</p>
<p>Who should not take methotrexate tablets?</p> <p>Do not take methotrexate tablets if:</p> <ul style="list-style-type: none"> • you are pregnant or planning to become pregnant. Methotrexate tablets can cause birth defects or death to your unborn child. See “What is the most important information I should know about methotrexate tablets?” • you are breastfeeding. Methotrexate tablets can harm your baby. You will need to decide either to breastfeed or to take methotrexate tablets, but not both. • you have any conditions that weaken your immune system (immunodeficiency conditions). • your bone marrow does not make enough blood cells, or if you have low white blood cell counts, low platelet counts, or serious anemia. • you drink alcohol or have liver problems from alcohol abuse. • you have chronic liver disease. • you are allergic to methotrexate or any of the ingredients in methotrexate tablets. See the end of this leaflet for a complete list of ingredients in methotrexate.
<p>Before using methotrexate tablets tell your doctor:</p> <ul style="list-style-type: none"> • about all your medical problems including if you: <ul style="list-style-type: none"> • have kidney problems or are getting dialysis treatments • have liver problems • have fluid in your stomach area (ascites) • have lung problems or fluid in your lungs (pleural effusion) • about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Methotrexate tablets and certain other medicines can affect each other and cause serious side effects. Do not start or change any medicines unless you have talked to your doctor and your doctor has told you it is safe. Know all the medicines that you take and keep a list of them with you at all times to show doctors and pharmacists.
<p>How should I take methotrexate tablets?</p> <ul style="list-style-type: none"> • Take methotrexate tablets exactly as prescribed by your doctor. Your dose of methotrexate tablets and when you take it will depend on the condition that is being treated. Do not take more methotrexate tablets than prescribed. Do not change your dose of methotrexate tablets unless your doctor has told you to. For treatment of severe psoriasis, and severe rheumatoid arthritis including juvenile rheumatoid arthritis, methotrexate tablets should be taken weekly, not every day. This weekly dose is taken either at one time or in several doses. • If you miss a dose of methotrexate tablets call your doctor to ask if you should take the dose or not. • If you take too much methotrexate tablets call your doctor or go to your nearest emergency room right away. You will need to take a medicine called an antidote as soon as possible. • Call your doctor right away for further instructions if you get dehydrated (lose a large amount of body fluids). This can happen if you are sick and have a fever, vomiting, or diarrhea. Dehydration can also happen when you sweat a lot with activities or exercise and don't drink enough fluids. • Stop taking methotrexate tablets if you get diarrhea, or if you get sores in your mouth. Call your doctor right away. If you keep taking methotrexate with these symptoms, you could get serious bleeding or tearing of your digestive tract. • Your doctor should do regular tests to monitor how methotrexate tablets are affecting your body. Check with your doctor after having any blood tests before taking methotrexate tablets again. Your doctor will tell you if it is safe to take more methotrexate tablets. • Certain side effects such as mouth sores may be reduced by folate supplementation with methotrexate tablets.

■ Black A/s: 150 x 320 mm

		Product Name	Component	Item Code	Date & Time
		Methotrexate Tablets	PIS	P1523697	06.02.2020 & 2:40 PM
Team Leader: Kiran Kulkarni Initiator: Srinivas A.		Customer / Country	Version No.	Reason Of Issue	Reviewed / Approved by
		Eugia Pharma_USA	00	Revision	
Artist: 		Dimensions	Colours :		
Additional Information : Supersede Item Code: P1514465		150 x 320 mm	No of Colours : 01		
Pharmacode NA					Sign / Date

What should I avoid while taking methotrexate tablets?**Do not:**

- **get pregnant or try to become pregnant.** See “What is the most important information I should know about methotrexate tablets?”
- **breastfeed.** See “Who should not take methotrexate tablets?”
- **drink alcohol.** Alcohol drinks, including beer and wine, may increase some of the side effects with methotrexate tablets, including the chance of liver damage.
- **take certain live virus vaccines.**

What are the possible or reasonably likely side effects of methotrexate tablets?

Methotrexate tablets can cause serious and life-threatening problems including (see “What is the most important information I should know about methotrexate tablets?):

- **birth defects and death of an unborn child**
- **serious anemia, lower white cells, red cells, and platelets in your blood**
- **liver damage**
- **kidney damage**
- **lung disease**
- **cancer of the lymph system (lymphoma)**
- **severe skin reactions and rashes**
- **opportunistic infections such as *Pneumocystis carini* pneumonia**
- **soft tissue and bone damage** if you are getting radiation therapy at the same time you are taking methotrexate tablets

The most common side effects of methotrexate tablets include:

- mouth sores
- low white blood cells
- nausea, upset stomach
- feeling poorly
- tiredness, chills, fever, dizziness
- higher chance for getting infections
- diarrhea
- vomiting
- hair loss
- easy bruising

Stop taking methotrexate tablets and call your doctor right away if you get diarrhea, mouth sores, a fever, dehydration, cough, bleeding, shortness of breath, any signs of infection, or a skin rash. If you have any questions about these or other side effects, talk to your doctor. These are not all the side effects of methotrexate tablets. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store methotrexate tablets?

- Store methotrexate tablets at room temperature between 68° to 77°F (20° to 25°C).
- Keep methotrexate tablets away from light.
- Keep methotrexate tablets and all medicines out of the reach of children.

General information about methotrexate tablets

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use methotrexate for a condition for which it was not prescribed. Do not give methotrexate tablets to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarizes the most important information about methotrexate tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about methotrexate tablets that is written for healthcare professionals.

For additional information, please contact Aurobindo Pharma USA, Inc. at 1-866-850-2876.

What are the ingredients in methotrexate tablets?

Active Ingredient: methotrexate disodium

Inactive Ingredients: lactose monohydrate, magnesium stearate and pregelatinized starch (maize).

Dispense with Patient Information available at: www.aurobindousa.com/product-medication-guides

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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