What is the most important information I should know about RHEUMATREX®?

• RHEUMATREX® can cause serious side effects that may be life-threatening (see "What are the possible or reasonably likely side effects of RHEUMATREX®?"). Most side effects can be found by medical tests before they become serious. Your doctor may do regular tests to check how RHEUMATREX® is affecting your body. It is important that you stay under a doctor's care while taking RHEUMATREX®. Call your doctor right away to report any side effects or symptoms you get.

• RHEUMATREX® 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 RHEUMATREX®. Neither you nor your partner should become pregnant while taking RHEUMATREX®. Women should wait at least 1 menstrual cycle after stopping treatment with RHEUMATREX® before getting pregnant. Men should wait at least 3 months after stopping treatment with RHEUMATREX® before getting their partner pregnant. Women who can become pregnant should have a pregnancy test before starting RHEUMATREX®. During treatment with RHEUMATREX® men whose partners and women who are able to get pregnant should use effective birth control.

What is RHEUMATREX®?

RHEUMATREX® is a prescription medicine used in treating certain cancers, severe rheumatoid arthritis including polyarticular juvenile rheumatoid arthritis, and severe psoriasis.

Who should not take RHEUMATREX®?

Do not take RHEUMATREX® if:

• you are pregnant or planning to become pregnant. RHEUMATREX® can cause birth defects or death to your unborn child. See "What is the most important information I should know about RHEUMATREX®?"

• you are breast-feeding. RHEUMATREX® can harm your baby. You will need to decide either to breast-feed or to take RHEUMATREX®, 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 RHEUMATREX®. See the end of this leaflet for a complete list of ingredients in RHEUMATREX®.

Before using RHEUMATREX® tell your doctor

• about all your medical problems including if you:
  • 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 non-prescription medicines, vitamins and herbal supplements. RHEUMATREX® 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.
How should I take RHEUMATREX®?

• Take RHEUMATREX® exactly as prescribed by your doctor. Your dose of RHEUMATREX® and when you take it will depend on the condition that is being treated. Do not take more RHEUMATREX® than prescribed. Do not change your dose of RHEUMATREX® unless your doctor has told you to. For treatment of severe psoriasis, and severe rheumatoid arthritis including juvenile rheumatoid arthritis, RHEUMATREX® should be taken weekly, not every day. This weekly dose is taken either at one time or in several doses. The RHEUMATREX® Dose Pack may help you remember to take the right dose of medicine on this weekly schedule.

• If you miss a dose of RHEUMATREX®, call your doctor to ask if you should take the dose or not.

• If you take too much RHEUMATREX® 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 RHEUMATREX® if you get diarrhea, or if you get sores in your mouth. Call your doctor right away. If you keep taking RHEUMATREX® with these symptoms, you could get serious bleeding or tearing of your digestive tract.

• Your doctor should do regular tests to monitor how RHEUMATREX® is affecting your body. Check with your doctor after having any blood tests before taking RHEUMATREX® again. Your doctor will tell you if it is safe to take more RHEUMATREX®.

• Certain side effects such as mouth sores may be reduced by folate supplementation with RHEUMATREX®.

What should I avoid while taking RHEUMATREX®?

Do not:
• get pregnant or try to become pregnant. See "What is the most important information I should know about RHEUMATREX®?"

• breast-feed. See "Who should not take RHEUMATREX®?"

• drink alcohol. Alcohol drinks, including beer and wine, may increase some of the side effects with RHEUMATREX®, including the chance of liver damage.

• take certain live virus vaccines.

What are the possible or reasonably likely side effects of RHEUMATREX®?

RHEUMATREX® can cause serious and life-threatening problems including (see "What is the most important information I should know about RHEUMATREX®?"):
• 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 RHEUMATREX®

The most common side effects of RHEUMATREX® 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 RHEUMATREX® 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 effect of RHEUMATREX®. 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 RHEUMATREX®?
• Store RHEUMATREX® at room temperature between 68° to 77° F (20° to 25° C).
• Keep RHEUMATREX® away from light.
• Keep RHEUMATREX® and all medicines out of the reach of children.

General information about RHEUMATREX®
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use RHEUMATREX® for a condition for which it was not prescribed. Do not give RHEUMATREX® 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 RHEUMATREX®. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about RHEUMATREX® that is written for healthcare professionals. For additional information, please contact DAVA Pharmaceuticals, Inc. at our toll free number: 877-963-8422.

What are the ingredients in RHEUMATREX®?
Active Ingredient: methotrexate sodium
Inactive Ingredients: lactose, magnesium stearate and pregelatinized starch.
This Medication Guide has been approved by the U.S. Food and Drug Administration.
Manufactured for:
DAVA Pharmaceuticals, Inc.
Fort Lee, NJ 07024 USA

By:
EXCELLA GmbH
Feucht, Germany
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