

Drug : **OTREXUP INJ**

What is this medicine?

METHOTREXATE (METH oh TREX ate) is a cytotoxic drug that also suppresses the immune system. It is used to treat psoriasis and rheumatoid arthritis.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

What should I tell my health care provider before I take this medicine?

They need to know if you have any of these conditions: -fluid in the stomach area or lungs -if you often drink alcohol -infection or immune system problems -kidney disease -liver disease -low blood counts, like low white cell, platelet, or red cell counts -lung disease -radiation therapy -stomach ulcers -ulcerative colitis -an unusual or allergic reaction to methotrexate, other medicines, foods, dyes, or preservatives -pregnant or trying to get pregnant -breast-feeding

How should I use this medicine?

This medicine is for injection under the skin. You will be taught how to prepare and give this medicine. Refer to the Instructions for Use that come with your medication packaging. Use exactly as directed. Take your medicine at regular intervals. Do not take your medicine more often than directed. This medicine should be taken weekly, NOT daily. It is important that you put your used needles and syringes in a special sharps container. Do not put them in a trash can. If you do not have a sharps container, call your pharmacist or healthcare provider to get one. Talk to your pediatrician regarding the use of this medicine in children. While this drug may be prescribed for children as young as 2 years for selected conditions, precautions do apply.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.

NOTE: This medicine is only for you. Do not share this medicine with others.

What if I miss a dose?

If you are not sure if this medicine was injected or if you have a hard time giving the injection, do not inject another dose. Talk with your doctor or health care professional.

Where should I keep my medicine?

Keep out of the reach of children. You will be instructed on how to store this medicine. Throw away any unused medicine after the expiration date on the label.

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine, talk to your doctor, pharmacist, or health care provider.

What should I watch for while using this medicine?

Avoid alcoholic drinks. This medicine can make you more sensitive to the sun. Keep out of the sun. If you cannot avoid being in the sun, wear protective clothing and use sunscreen. Do not use sun lamps or tanning beds/booths. You may get drowsy or dizzy. Do not drive, use machinery, or do anything that needs mental alertness until you know how this medicine affects you. Do not stand or sit up quickly, especially if you are an older patient. This reduces the risk of dizzy or fainting spells. You may need blood work done while you are taking this medicine. Call your doctor or health care professional for advice if you get a fever, chills or sore throat, or other symptoms of a cold or flu. Do not treat yourself. This drug decreases your body's ability to fight infections. Try to avoid being around people who are sick. This medicine may increase your risk to bruise or bleed. Call your doctor or health care professional if you notice any unusual bleeding. Check with your doctor or health care professional if you get an attack of severe diarrhea, nausea and vomiting, or if you sweat a lot. The loss of too much body fluid can make it dangerous for you to take this medicine. Talk to your doctor about your risk of cancer. You may be more at risk for certain types of cancers if you take this medicine. Both men and women must use effective birth control with this medicine. Do not become pregnant while taking this medicine or until at least 1 normal menstrual cycle has occurred after stopping it. Women should inform their doctor if they wish to become pregnant or think they might be pregnant. Men should not

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father a child while taking this medicine and for 3 months after stopping it. There is a potential for serious side effects to an unborn child. Talk to your health care professional or pharmacist for more information. Do not breast-feed an infant while taking this medicine.

What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible: -allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue -breathing problems or shortness of breath -diarrhea -dry, nonproductive cough -low blood counts - this medicine may decrease the number of white blood cells, red blood cells and platelets. You may be at increased risk of infections and bleeding -mouth sores -redness, blistering, peeling or loosening of the skin, including inside the mouth -signs of infection - fever or chills, cough, sore throat, pain or difficulty passing urine -signs and symptoms of bleeding such as bloody or black, tarry stools; red or dark-brown urine; spitting up blood or brown material that looks like coffee grounds; red spots on the skin; unusual bruising or bleeding from the eye, gums, or nose -signs and symptoms of kidney injury like trouble passing urine or change in the amount of urine -signs and symptoms of liver injury like dark yellow or brown urine; general ill feeling or flu-like symptoms; light-colored stools; loss of appetite; nausea; right upper belly pain; unusually weak or tired; yellowing of the eyes or skin Side effects that usually do not require medical attention (Report these to your doctor or health care professional if they continue or are bothersome.): -dizziness -hair loss -headache -stomach pain -upset stomach -vomiting

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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