

Informed Consent for the Use of Methotrexate

What is Methotrexate?

Methotrexate was first developed to treat certain types of cancer. It is now used in much lower doses to treat rheumatoid arthritis, psoriatic arthritis, and inflammatory bowel disease.

How Does Methotrexate work?

It alters the way your body uses folic acid, which is necessary for cell growth. It also decreases inflammation. Scientists suspect that these actions account for the beneficial effects on inflammatory bowel disease.

How is Methotrexate taken?

Methotrexate is taken once weekly usually by injection. The dose is usually between 15-25 mg per week. It should not be taken more often than one day per week. More frequent administration can be associated with serious side effects. You should take the medication on the same day of each week. If you become confused about when to take it, you should call your doctor before you take the next dose. If you miss a dose, do not take the missed dose and do not double the next dose. Just continue your regular dosing schedule and check with your doctor.

What are the Side Effects of Methotrexate?

The most common side effects are upset stomach, nausea, vomiting, loss of appetite, diarrhea, and mouth sores. If these develop you should contact your doctor. A change in the dose or how you take the medication may reduce these side effects.

Less common side effects include headaches, dizziness, mood alterations, skin rashes and unexplained weight loss. Increased sensitivity to the sun has also been observed, although this is rare. You could have a decrease in white blood cells that help fight infection. A decrease in the platelet count or red blood cell count could also occur, which could lead to bruising, bleeding, or fatigue. These blood count changes are rare if you are on weekly low doses of methotrexate. However, if you have a pre-existing kidney disease, low levels of folic acid, certain infections or if you use certain medications, including an antibiotic called trimethoprim/sulfamethoxazole (Bactrim, Septra, Cotrim), the possibility of these blood cell changes are increased.

Rarely, lung damage can occur. If you develop cough, progressive shortness of breath, or fever you should call the doctor right away.

Methotrexate can cause liver damage. Drinking alcohol regularly can increase the risk of liver damage. Alcohol should be discontinued while taking methotrexate.

Do not get any immunizations (vaccinations) without your doctor's approval. Methotrexate may lower your body's resistance, and you might get the infection the immunization is trying to prevent.

If you get the flu or another infection, call your doctor right away to find out if you should continue your methotrexate while you are sick. Dehydration can increase your risk of side effects.

Tell your doctor if you are allergic to any medications, are taking other medications, including vitamins or over-the-counter drugs, or if you have any other medical conditions, especially kidney, liver, or lung disease.

How are the side effects monitored?

To reduce the potential for side effects from methotrexate, regular lab testing is necessary. Prior to starting, standard blood tests may be performed. A chest X-ray may also be recommended. Once on treatment, regular follow-up and blood tests are performed. Keeping regular lab and office appointments is essential because many side effects can be detected before they become serious.

Attention Women of Childbearing Age and Men Considering Fathering a Child

Methotrexate may cause birth defects if taken by women at the time of conception or during pregnancy. Women of child bearing potential **MUST** use birth control and must **not** get pregnant while receiving this drug. After methotrexate is stopped, you must wait at least one menstrual cycle before attempting to get pregnant. This drug has no effect on fertility, and if the drug is stopped at least 30 days before trying to become pregnant, the unborn child will not be affected.

Breast feeding should be avoided while taking methotrexate, because the medicine is passed to a baby through the mother’s milk.

Methotrexate may lower a man’s sperm count. However, it will return to normal after the medication is stopped. Researchers are currently exploring whether birth defects may be related to a man taking methotrexate at the time of conception. In the meantime, men must stop taking methotrexate three months before attempting conception.

I have read, understand, and agree to the terms of this document.

Patient Printed Name

Printed Name of Witness

Patient Signature

Witness Signature