

# Children's Centerfor Digestive Health Care, L.L.C.

# What familes need to know about Methotrexate therapy

## 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, either by mouth or by injection. Most patients respond within 1month. Typically, the dose is based on a patient's weight:

20-29kg -10mg

30-39kg -15mg

40-49kg -20mg

>49kg -25mg

\*\*The exact dosage will be determined by your doctor and some variation in these doses is common. In some patients, a much lower dose is used when methotrexate is used in combination with anti-TNF therapy (eg. Remicade®, Humira®, Cimzia®).

Patients taking methotrexate often receive folic acid supplementation.

Methotrexate should not be taken more often than once 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?

Many patients have no apparent side effects. The most common side effects are upset stomach, nausea, vomiting, loss of appetite, diarrhea, and mouth sores. To minimize side effects, many take their medication on either Friday or Saturday night so they can sleep in the next morning. Also, with initial dosing, medications for nausea like Zofran®, are often given.

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 in some patients. Drinking alcohol regularly can increase the risk of liver damage. Alcohol should be discontinued while taking methotrexate.

Immunosuppression: Avoid "live-virus" vaccines unless given permission by your GI doctor. Examples of these vaccines include the ones for chickenpox (varicella), mumps/measles/rubella (MMR), NASAL flu mist, oral polio, yellow fever, rotavirus, and oral typhoid. 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.

<u>Avoid non-steroidal analgesics while taking methotrexate</u>. These drugs include, including aspirin, motrin, advil, ibuprofen, and naproxen. Combined use of these medications with methotrexate can increase kidney problems.

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.

## Precaution -- Need to avoid pregnancy while on methotrexate

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 methotrextate is stopped, you must

wait at least one menstrual cycle before attempting to get pregnant. If the drug is stopped at least 30 days before trying to become pregnant, the unborn child will not be affected.

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 talking methotrexate at the time of conception. In the meantime, men must stop taking methotrexate three months before attempting conception.

## **Methotrexate Effectiveness**

Due to relatively few studies in pediatric populations the exact effectiveness of methotrexate in children in not clear. In a one study in 2010, 48% of patients were in remission at 6 months. In a study, in 2007, 42% were able to achieve remission with methotrexate and 50% had a response. In these and other studies, patients usually respond within four to six weeks of initiation.

## Conclusion

Methotrexate remains an important medication for controlling inflammatory bowel disease. In some patients, it is administered by itself (monotherapy) and in others it is used to increase the effectiveness of anti-TNF therapy (cotherapy). It is crucial to give only once a week. It is given much less often to females with IBD than males because of concerns of causing birth defects if the patient became pregnant. Due to the potential for side effects, close monitoring is recommended along with keeping all medical appointments

Updated December 2011