

## Patient Information Sheet

### Methotrexate for Inflammatory Bowel Disease (brand name = Methotrexate®)

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#### What is Methotrexate?

Methotrexate is a drug that reduces inflammation and the body's response to this inflammation. It is also used as chemotherapy to slow cell growth, in the treatment of cancer. Methotrexate can be taken orally as a pill or can be given as an injection. This will be up to your IBD physician's discretion.

#### When is Methotrexate used?

Methotrexate is useful in treating Crohn's disease that has not responded to previous medications, such as prednisone or 5-ASA products. Methotrexate can help some patients permanently transition off of prednisone. Methotrexate may not work on all patients and the decision to use Methotrexate must be made by your physician, who will determine this on a case-by-case basis. Methotrexate is also used together with anti-TNF biologic therapies (infliximab/Remicade® or adalimumab/Humira®) to improve and prolong their effectiveness.

#### What are the side effects of Methotrexate?

1. Common minor side effects include nausea, mouth ulcers and skin rash. Consider taking this medication at bedtime on your scheduled day of dosing to minimize nausea. You can talk to your IBD practitioner about taking this medication in scheduled divided doses. Frequent small meals and snacks may also help. Practice good oral care by seeing your dentist regularly, using a toothbrush with soft bristles, gargling with soda water, or using a non-alcohol mouthwash. If mouth sores worsen, you should contact your IBD health practitioner.
2. Mild lowering of the red blood cell and white blood cell count is common with methotrexate. Your red and white blood cell counts will be monitored. If they fall below a certain level, the methotrexate will be stopped to allow the counts to return to normal.
3. Liver scarring. If methotrexate is administered in very large doses (>25 mg per week) or given too frequently (e.g., daily), there is a 10% to 30% chance of liver scarring. If the dose of methotrexate is kept low and given on a once weekly basis, the risk of liver scarring is extremely low. Liver blood tests will be monitored to ensure that liver scarring does not occur.
4. Lung scarring. This is a very uncommon side effect of methotrexate that presents with a shortness of breath. Withdrawing the methotrexate and treating the shortness of breath with steroids leads to resolution.
5. Birth defects or fetal death. It is extremely important that you do not become pregnant while on methotrexate since birth defects have been shown to occur. Effective birth control must be used at all times by female patients when taking this medication, and must be continued after stopping methotrexate until the drug has been completely cleared by the body; the recommended time period should be discussed with your IBD practitioner but ideally pregnancy should be avoided for 6 months after stopping the medication. If you are a female patient and become pregnant while taking methotrexate, **you must immediately contact your IBD health practitioner.**
6. Mild hair loss can occur. Speak with your IBD health practitioner if your hair loss is increasing or becoming problematic for you.

**You should stop this medication and contact your IBD health practitioner immediately** to report symptoms of severe nausea with or without vomiting, fever, new skin rash or other skin reaction such as blistering or peeling, unusual bleeding or bruising, unusual tiredness or weakness, joint pain, malaise, muscle ache, kidney problems, pain with urination, dizziness or feeling faint especially when standing up, vomiting blood, black or tarry stools, increasing blood in your stools, increasing abdominal pain since starting methotrexate, and/or diarrhea that has increased since starting the medication, as this may indicate hypersensitivity, intolerance, or allergy to this medication. **If your symptoms are severe or worsening, you should go immediately to the nearest emergency department or activate your emergency response system. You should immediately contact your IBD health practitioner if you develop** fever, a dry non-productive cough, shortness of breath and/or chest pain, as these may be symptoms of drug toxicity.

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### When will I get blood tests?

It is important to have regular lab work done with the guidance of your IBD health practitioner. You will need to complete bloodwork every week for four weeks after starting methotrexate, and then every month for the entire time you are taking methotrexate.

### Will my IBD health practitioner monitor my side effects?

Yes, you will have regular visits with your IBD health practitioner.

### Prevention of Adverse Events and Management of Side Effects:

- Methotrexate is taken on a weekly basis and should never be taken every day.
- Before starting this medication, you should inform your IBD health practitioner if you have a history of any problems or concerns with your liver (including hepatitis), kidney, lungs, nervous system, stomach or intestinal ulcers, alcohol abuse or alcoholism, persistent bloodwork abnormalities, or chronic recurrent infections.
- Consuming alcohol while taking methotrexate can increase the risk of liver injury.
- Taking **folic acid** can help to minimize the side effects associated with methotrexate therapy. Folic acid is typically taken every day, except for the day of the week that you take your methotrexate. The usual dosage of folic acid is 1 mg daily, unless instructed otherwise by your IBD health practitioner.
- Methotrexate can interact with other medications (e.g., antibiotics) which can increase the risk of methotrexate toxicity. Contact your family physician if you are prescribed any new medications. When filling any drug prescription or purchasing over-the-counter medications, vitamins or herbal supplements, let your pharmacist know that you are taking methotrexate so that potential interactions can be identified.
- To avoid potentially severe side effects due to drug toxicity, you should not take pain medications called non-steroidal anti-inflammatories (NSAIDs), unless instructed by your IBD health practitioner. Some examples of NSAIDs are ibuprofen, naproxen, diclofenac, Advil, Motrin, Aleve and Naprosyn. You should speak with your family physician or pharmacist if you have questions about pain medications or anti-inflammatories that are safe to use when taking methotrexate.
- Methotrexate cannot be taken by women during pregnancy or when trying to get pregnant. Males who are taking methotrexate and who are planning for a pregnancy with their female partner should discuss this decision with their IBD health practitioner, as there are different opinions on the safety of methotrexate in males trying to conceive. Females should not breastfeed when taking methotrexate.