

METHOTREXATE

Medication Information

This information is intended as a guide only. Ask your doctor if you have any questions relating to this information.

WHAT IS METHOTREXATE AND HOW DOES IT WORK?

Methotrexate slows the production of new cells by the body's immune system and by doing this it suppresses the body's immune attack on the bowel wall. It is used to treat inflammatory bowel disease (IBD), both for Crohn's disease and ulcerative colitis.

Methotrexate has been used to treat IBD for many years (>20 years) and has been shown to be a generally safe and effective therapy.

HOW LONG WILL I NEED TO TAKE METHOTREXATE BEFORE IT HAS AN EFFECT?

Methotrexate does not have an immediate effect. It may take up to 3 months to reach the maximal benefit from the medication. You will usually notice some improvement in your symptoms within 4 weeks after starting Methotrexate.

WHEN SHOULD I TAKE METHOTREXATE?

Methotrexate is usually taken once per week. It is useful to take Methotrexate on the same day each week (e.g. Methotrexate Monday) to help you to remember to take it.

It is usually given as a subcutaneous injection (under the skin) but may be given in tablet form once you are well established on the medication.

If you miss taking Methotrexate on your normal day, you can take it within 48 hours. However, if you are more than three days late you should not take the Methotrexate that week. You should take your next dose on the usual day the following week.

WHAT DOSE OF METHOTREXATE SHOULD I TAKE?

Your doctor will advise you on the weekly dose. Usually a larger dose is initially prescribed and then a lower regular dose is continued after the first month.

A common regime is 25mg of Methotrexate weekly for 4 weeks and then 12.5mg of Methotrexate weekly thereafter.

The dose may be adjusted depending on your response to treatment or any side effects that you experience.

WHY AM I PRESCRIBED FOLIC ACID?

Folic acid is a vitamin that helps your body tolerate Methotrexate, and also reduces the risk of side effects.

You should take the Folic acid every day EXCEPT the day you take the Methotrexate.

WHAT ARE THE RISKS OF TAKING METHOTREXATE?

Most patients will tolerate Methotrexate. However, as with all medications there are potential side effects and it is important that you are aware of these. Close monitoring is important to reduce the risk of harm with these medications. Your doctor will discuss these risks with you, and the steps to be taken to reduce the likelihood of side effects occurring. Below is a list of some (but not all) risks of Methotrexate therapy.

More common

- Tiredness
- Nausea, vomiting and reduced appetite
- Mouth ulcers

- Diarrhoea

Less common

- Serious infection:
 - If you develop chicken pox or shingles while taking Methotrexate you should contact your gastroenterologist because you may require treatment
- Bone marrow suppression causing a reduction in white blood cells, platelets and anaemia. Monitoring your blood count regularly reduces this risk
- Lung or liver fibrosis. These are rare complications that usually only occur when the Methotrexate has been taken for a number of years
- Kidney injury. This is a rare complication at the lower doses used for IBD
- Reversible hair loss
- Skin rashes

You should see your doctor immediately if you develop any of the following, or if you are concerned that you are having any other side effects of Methotrexate:

- Mouth ulcers
- A fever, sore throat or any other sign of infection
- Nausea, vomiting, dark urine or abdominal pain
- Unexplained bruising or bleeding from the gums
- You become breathless or develop a cough

WHAT DO I NEED TO DO BEFORE I START TAKING METHOTREXATE?

Before starting Methotrexate, you will need to:

- discuss starting this medication and enlist their help with monitoring

- Take bloods tests:
 - Full blood count, liver function tests, kidney function tests
 - ensure that you do not have active or latent infection that could become more active during therapy
 - Varicella (chickenpox) serology. If you are not immune to chickenpox, you will need a vaccination prior to starting therapy
 - Tuberculosis
- Have a chest x-ray
- Vaccination:
 - **Pneumococcal** vaccination (Pneumovax®) - 5 yearly.
 - **Influenza** vaccination (Fluvax®) - yearly.
 - **Varicella** vaccination (Once - if you have not had chicken pox).
 - **Human Papilloma** vaccination (Once - for females who are not yet sexually active).
- Ensure that your pap smears are up to date.
- Discuss your plans for pregnancy or whether you are thinking of starting a family.

You can not take methotrexate if you are pregnant or are thinking of starting a family in the next 3 months (both males & females).

Your doctor will:

- Review your medical history, particular with regard to any previous infection or cancer.
- Review your medications to see if you are taking any other medicines that could interact with Methotrexate. Examples include:
 - Certain antibiotics, such as trimethoprim and cotrimethoprim, sulphasalazine and
 - non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen and aspirin.

It is important to inform your doctor and pharmacist that you are taking Methotrexate when you are prescribed a new medication.

WHAT DO I NEED TO DO AFTER STARTING METHOTREXATE?

Close monitoring is important to keep you safe while taking Methotrexate, particularly blood tests to monitor your full blood count and liver function. Monitoring helps to keep you safe and minimise any risks of harm related to therapy.

After starting Methotrexate, you will be asked to:

- Make an appointment with your GP and inform them that you are starting this medication.
- Have regular blood tests. These will be scheduled (full blood count and liver function tests):
 - Weekly for the first 4 weeks.
 - Monthly for next 3 months.
 - 3 monthly thereafter (for as long as you are on treatment).
 - You must not take Methotrexate unless you are having regular blood monitoring.
 - The blood test request form we give you can be used repeatedly for 1 year.
- Take regular folic acid every day that you are not taking methotrexate.
- Inform your doctor if you have any side effects, in particular easy bruising, fever, or pain.
- Use two forms of contraception
 - Methotrexate is the only IBD medication that is **not advised** for people who wish to have children in the near future.
 - Women must not take Methotrexate if considering pregnancy or during pregnancy. **It is likely to harm the unborn baby.** Methotrexate can also reduce fertility in men and can lead to foetal malformation. Women and men should take 2 forms of

effective contraception while taking Methotrexate and for at least 3 months after stopping Methotrexate.

- Not breast feed if you take Methotrexate as it passes into breast milk.
- Ensure that you are up to date with your vaccinations:
 - **Pneumococcal** vaccination (Pneumovax®) - 3 yearly.
 - **Influenza** vaccination (Fluvax®) - yearly.
 - **Avoid live vaccines** (MMR (measles, mumps and rubella), polio, yellow fever, Japanese encephalitis and BCG (tuberculosis). **These are dangerous** while taking Methotrexate and should be avoided. Inactivated vaccines such as the flu vaccination are perfectly safe and recommended.
- Limit alcohol:
 - Alcohol and Methotrexate can interact and damage the liver and so alcohol consumption should be kept to a minimum and well below the standard recommended levels while you are taking Methotrexate.
- Take care in the sun. Methotrexate makes you more sensitive to the sun and you will burn more easily.

Please contact your doctor if you have any concerns.