

Methotrexate

This information leaflet aims to answer common questions you may have if you have been given methotrexate to treat your Crohn's Disease or Ulcerative Colitis (UC), together known as Inflammatory Bowel Disease (IBD). You can obtain further information from your pharmacist or doctor or from the information leaflet supplied with your prescription or from the website: www.medicines.org.uk.

Why have I been started on this medicine?

Methotrexate may be given to you if you keep getting relapses while on standard treatments, usually aminosalicylates (5-ASAs) and steroids, or if you have had an adverse reaction to either azathioprine or 6-mercaptopurine. It is widely used to treat Crohn's Disease, but less commonly for Ulcerative Colitis.

How does it work?

Methotrexate is a type of medicine called an immunosuppressant. The immune system is important in fighting infections, but sometimes immune system cells attack the body's own tissues and trigger chronic inflammation. Methotrexate reduces inflammation in the bowel by dampening down the activity of these cells in the immune system.

How long will it take to work?

Methotrexate does not work immediately. It can take up to 3 months before your symptoms improve. Although you may not feel the benefit during this time it does not mean that the methotrexate is not working.

How long will I be taking methotrexate?

If you respond to methotrexate you will usually remain on it for many months and perhaps several years, as long as your blood tests are satisfactory.

When do I take methotrexate?

You must **only** take methotrexate as a single **ONCE A WEEK dose** on the same day each week.

If you forget to take your methotrexate on your normal day, you can take it up to two days later. Do not take it if you are three or more days late. Take your next dose on your usual day the following week.

How is it taken?

Weekly, in tablet form or by injection.

Tablets:

You should take the tablets by mouth, after food. Swallow the tablets whole with a glass of water. Do not crush or chew them.

Injection:

Your nurse may train you to inject the methotrexate yourself. Alternatively the nurse may give you the injection each week.

What is the normal dosage?

The dosage of methotrexate varies according to your individual circumstances. The range is typically from 12.5 mg (milligram) a week to 25 mg a week. Some specialists start at a low dose of 10mg to make sure that the treatment is tolerated and, if so, increase the dose to a maximum of 25mg.

Methotrexate tablets come in two different strengths: 2.5mg and 10mg. The shape is different but the colour is very similar. It is important that you take the correct strength and dose of tablets. If you think you have the wrong strength, do not use your medicine before checking with your doctor, pharmacist or nurse.

Some hospitals and doctors have agreed to only use the 2.5mg strength to prevent any confusion; your doctor, pharmacist or nurse will be able to tell you if this has been agreed in your area.

Why am I prescribed folic acid?

Folic acid is a vitamin that helps your body to cope with methotrexate and also helps to reduce some of the possible side effects, such as nausea. Usually it is taken once a week, but **not** on the same day as methotrexate, but a number of different regimes may be used and some people are asked to take folic acid every day, except the methotrexate day.

How effective and safe is methotrexate?

Methotrexate has been used to treat Crohn's Disease for some 20 years and has been successful in treating Rheumatoid Arthritis for over 50 years. Research studies on this drug for IBD are relatively small and limited. A review of these studies found that higher weekly doses of 25mg by injection may be more effective than lower oral doses, but some people use oral preparations because of the convenience. Mild side effects, usually nausea and vomiting, were more common with higher doses, but generally there were no severe side effects. Approximately one out of ten people with IBD taking methotrexate stops treatment because of side effects.

There is little research on the use of methotrexate for Ulcerative Colitis, but the limited trials suggest it may be effective in higher doses.

Will I need any special checks?

Before you start treatment you will need to have blood tests, including liver and kidney tests, as methotrexate can affect the blood count and sometimes cause liver problems. Your doctor may also request a chest x-ray, lung function tests, and liver scans and biopsy. If your bone marrow, liver or kidney function is not working properly, methotrexate may not be suitable for you.

You will need to have regular blood counts and liver tests while you are on methotrexate to check that the treatment is working and that it is not affecting your blood and liver. In the first 2-3 months this will usually be every 2 weeks and then every 2-3 months thereafter.

The hospital should give you a booklet to record all your tests. Your hospital team may share your drug management with your GP. The record booklet helps everyone looking after you to share information, so you should take it with you every time you see your GP, hospital doctor, pharmacist or nurse.

Will I need to take any special precautions while on methotrexate?

Try to avoid contact with people who have infections. As methotrexate affects the way the body's immune system works, you may be more prone to infections. This means that even a mild infection such as a sore-throat could develop into a serious illness.

You may also be at risk of severe infection from the viruses which cause chickenpox and shingles, measles and pneumococcal disease. If you are not already immune you can be vaccinated before starting treatment. Otherwise tell your doctor or nurse as soon as possible if you come into contact with anyone who has any of these conditions and you may be able to have a protective injection.

Methotrexate may increase the skin's sensitivity to sunlight, therefore sunscreens should be used, and sunlamps or sunbeds should be avoided.

Can I take other medicines along with methotrexate?

Some medicines interact with methotrexate and could cause unexpected side effects. These medicines include certain antibiotics, trimethoprim and co-trimoxazole and non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin and ibuprofen. It is advisable to talk to your doctor or nurse specialist if you want to take NSAIDs.

It is important to tell your doctor, nurse specialist or pharmacist about all other medicines you are taking or thinking of taking, including over-the-counter medicines, herbal, complementary or alternative therapies.

You should always tell any other doctor or dentist treating you, that you are taking methotrexate.

Can I have immunisations while on methotrexate?

Certain vaccinations and immunisations may be unsafe to take together with methotrexate, which suppresses the immune system. You should not receive any of the **live** vaccines such as polio, yellow fever, BCG (tuberculosis), rubella (German measles) and MMR (measles, mumps and rubella) while taking methotrexate. An 'inactivated' polio vaccine can be given instead of the 'live' one.

Pneumovax and yearly flu vaccines are safe, as they are not live vaccines. The Chief Medical Officer recommends the flu vaccine for people on immunosuppressants. Close relatives and family members may have live vaccines without any risk to you.

Can I drink alcohol while taking methotrexate?

Alcohol and methotrexate can interact and affect your liver. When taking methotrexate medical opinion suggests you keep your intake of alcohol to well within the maximum limits. This is 2-3 units a day for women and 3-4 units a day for men.

Does methotrexate affect fertility or pregnancy?

As methotrexate can cause birth defects, it must not be taken when trying to conceive or during pregnancy. Doctors advise both men and women to use two forms of reliable contraception during treatment. Couples should avoid pregnancy if methotrexate has been taken by either partner within the last three to twelve months, as advised by your doctor. If you want to start a family or become pregnant, it is important to discuss this with your doctor.

What about breastfeeding?

Methotrexate passes into breast milk and potentially can affect the baby's immune system and can affect growth. For these reasons you should avoid breastfeeding while taking methotrexate.

What are the possible side effects?

All medicines can cause unwanted side effects, but we are all different and not everybody gets them. If you do, they usually improve as your body adjusts to the new medicine.

The more common side effects at the beginning of treatment are feeling sick, vomiting and diarrhoea. The following may help to reduce these symptoms:

- Make sure you take the prescribed vitamin supplement, folic acid or take it more often.
- Take methotrexate at a different time, such as at night before you go to bed.
- If you are taking the tablet, switch to the injection.
- Your doctor may be able to give you anti-sickness medication to take about an hour before your weekly dose of methotrexate.

Other side effects may include:

- Sore mouth and ulcers – Drinking plenty of fluids, and cleaning your teeth regularly and gently with a soft toothbrush can help to reduce the risk of this happening. Talk to your doctor or nurse if you have this problem, as you could take prescribed special mouthwashes and medicines to prevent or clear any mouth infection.
- Bruising or bleeding – Methotrexate may reduce the production of platelets in the bone marrow, which help with blood clotting. You may notice that you bruise very easily, or bleed freely, such as from blood spots or rashes on the skin, nosebleeds and bleeding gums. Tell your doctor about any new or unexplained bleeding or bruising before you take your next dose of methotrexate.
- Hair loss – this is usually slight and hair growth usually returns to normal once the treatment is stopped.

Rarely methotrexate can affect the lungs, causing an ongoing cough and shortness of breath. Contact your doctor or nurse immediately if you feel breathless when resting.

Methotrexate can damage the liver, and this may happen with very few outward signs. However in severe cases you may notice pain in the right side of your abdomen, nausea, loss of appetite, jaundice or severe itching of the skin. Blood tests can show up liver damage, but special scans and a biopsy of the liver may also be required.

As with most medications, there is a small chance that you may be allergic to or intolerant of methotrexate. Contact your doctor immediately if you develop any unexpected reaction soon after taking the medicine, such as:

- Skin rashes
- hives (swollen, red, itchy patches of skin)
- Swelling of the lips and mouth
- Headaches
- Nausea
- Vomiting
- Abdominal pain
- Shortness of breath
- Wheezing
- Light-headedness

Who should I talk to if I am worried?

If you are worried about taking methotrexate or you have any questions, contact your doctor or nurse specialist. You can discuss why it has been prescribed, what the correct dose and frequency is, what monitoring for adverse effects is in place, and what, if any, alternatives are available for you in your particular circumstance.

Where can I get further information?

You can contact our Information Service by email: nacc@nacc.org.uk or telephone the **NACC Information Line on 0845 130 2233** for further information. You can obtain more information about other drugs used in the treatment of IBD from NACC's booklet *Drugs used in IBD* and from other Drug Treatment Information leaflets. Please call the Information Line for copies or see the NACC website: www.nacc.org.uk to download Drug Treatment Information leaflets.

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Methotrexate – Edition 2

Last review May 2009

Next review due 2010

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The National Association for Colitis and Crohn's Disease (NACC) is a voluntary Association, established in 1979, which has 30,000 members and 70 Groups throughout the United Kingdom.

Membership of the Association costs £12 a year. New members who are on lower incomes due to their health or employment circumstances may join at a lower rate. Additional donations to help the work of the Association are always welcomed.