



INFORMATION SHEET

METHOTREXATE

INTRODUCTION

This information sheet is a brief overview of some of the important points about methotrexate for Crohn's Disease and Ulcerative Colitis (UC) (the two main forms of Inflammatory Bowel Disease - IBD). It is about methotrexate in general and is not intended to replace specific advice from your doctor or any other health professional. For further information, please talk to your doctor or specialist IBD team or look at the information sheet supplied with your medication or available on the website: www.medicines.org.uk/emc.

WHY AM I BEING TREATED WITH METHOTREXATE?

Methotrexate may be prescribed for you to induce or maintain remission for Crohn's Disease if you keep having relapses while on standard treatments for IBD, such as aminosalicylates (5-ASAs) and steroids, or if you have had an adverse reaction to either azathioprine or 6-mercaptopurine. Although currently unlicensed for use in IBD, it has been widely used to treat people with Crohn's, and rather less commonly people with Ulcerative Colitis. Methotrexate may also be given as combination therapy with biological medicines such as infliximab or adalimumab.

HOW DOES IT WORK?

Methotrexate belongs to a group of medicines called immunosuppressants. The immune system is important for fighting infections, but sometimes cells in the immune system attack the body's own tissues and trigger chronic inflammation like that found in IBD. Methotrexate reduces inflammation in the bowel by dampening down the activity of the immune system. However, this can mean you are more susceptible to infections. For more information see **Will I need to take any special precautions while on methotrexate?**

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 for some time, it does not mean that the methotrexate is not working. You will be given regular blood tests during this time.

HOW LONG WILL I BE TAKING METHOTREXATE?

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

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I was initially given tablets but I couldn't tolerate them. My doctor then prescribed the injections instead, which have been great.

”

Gemma, age 34
diagnosed with Crohn's Disease in
2014

WHEN AND HOW DO I TAKE METHOTREXATE?

Methotrexate is taken as a single ONCE A WEEK dose on the same day each week. It can be taken in two different ways – either by tablets or by injection. Sometimes people start off on the injection form, before moving to oral tablets.

- **Tablets:**

Taken by mouth, after food. The tablets should be swallowed whole with a glass of water while sitting upright or standing. Do not crush or chew them.

- **Injection:**

Methotrexate injections can be either subcutaneous (under the skin) or intra-muscular (into muscle). These can be given at the clinic by the nurse, or alternatively your nurse may train you to inject the methotrexate yourself.

If you forget to take your methotrexate on your normal day, ask your doctor or pharmacist for advice. You may be able to take it up to two days later, but you should not take it if you are three or more days late. If this happens, take your next dose on your usual day the following week. Do **not** double up your dose.

WHAT IS THE NORMAL DOSAGE?

Doctors and hospitals have different ways of prescribing methotrexate. Some doctors may recommend starting with weekly injections for 8-12 weeks to induce remission, and then move to weekly oral tablets if it is working well, while other doctors may recommend just the tablet form or the injection form.

Some specialists start at a low dose of methotrexate and slowly increase it to a maximum of 25mg a week, while other doctors may start at 25mg a week and slowly reduce it.

The methotrexate tablets come in two different strengths: 2.5mg and 10mg. The two strengths are different shapes, 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 use only the 2.5mg tablets to prevent any confusion. Your doctor, pharmacist or nurse will be able to tell you if this applies in your area. If you think you may have taken too much methotrexate, contact your doctor or go to your local Accident and Emergency department immediately.

WHY HAVE I ALSO BEEN PRESCRIBED FOLIC ACID?

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

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HOW EFFECTIVE AND SAFE IS METHOTREXATE?

Methotrexate has been used to treat Crohn’s Disease for some 25 years. Research has found that a weekly dose of 25mg by injection may induce remission in Crohn’s, while a lower dose of 15mg per week can maintain remission.

There is some evidence that taking methotrexate by injection is more effective and may cause fewer side effects than tablets when treating Crohn’s. However, some people prefer to use oral preparations because they are more convenient, and some doctors prescribe the oral tablets to maintain remission once remission has been induced by the injections.

Research on the use of methotrexate for Ulcerative Colitis is limited, partially because many of the studies looked at a very low oral dose of methotrexate. However, medical experience suggests that it can be beneficial for some people with UC.

Sometimes methotrexate is used in combination with biological drugs such as infliximab or adalimumab. However, the evidence for this is mixed, some studies suggest that methotrexate reduces the risk of developing antibodies to the biological drug and makes it work better, but other studies do not show any benefit.

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WILL I NEED ANY SPECIAL CHECKS BEFORE I START TAKING METHOTREXATE?

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, or liver scans. If your bone marrow, liver or kidney function is not working properly, methotrexate may not be suitable for you. If you haven’t had chicken pox or shingles before, you may be tested to see if you are immune to the virus that causes them, and you may be given a vaccine to protect you from catching the virus before you start taking methotrexate. If you are female, you may be asked to take a pregnancy test before you start taking the drug because methotrexate can be harmful to the unborn baby.

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WILL I NEED ONGOING CHECKS WHILE I AM TAKING METHOTREXATE?

You will need to have regular blood counts and liver tests while you are on methotrexate to check that the treatment is not affecting your blood or liver. A typical approach may be to have blood tests every 1-2 weeks for the first 2 or 3 months until therapy is stabilised, and then every 1-3 months thereafter. This can show whether you are developing side effects to the methotrexate.

Your treatment monitoring may be managed by your hospital team or shared between the hospital and your GP. You may be given a booklet to record your test results. Take this with you every time you see your GP, hospital doctor, dentist, specialist nurse or pharmacist, as sharing information helps you to receive safer care.

WILL I NEED TO TAKE ANY SPECIAL PRECAUTIONS WHILE ON METHOTREXATE?

Try to avoid close contact with people with infections. Methotrexate affects the way the body's immune system works, which can make you more prone to infections. Even a mild infection, such as a cold or sore throat, could develop into a serious illness. Contact your doctor if you begin to feel unwell and think you have developed an infection, or are experiencing any other side effects (see **What are the possible side effects?**)

You may also be at greater risk of becoming more seriously ill from the viruses which cause chickenpox and shingles, measles and pneumococcal disease. If you are not already immune you may be able to 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, as you may be able to have a protective injection for some viruses.

As with all medicines, avoid driving and hazardous work until you have learned how methotrexate affects you, as it can occasionally cause fatigue or confusion.

CAN I TAKE OTHER MEDICINES ALONG WITH METHOTREXATE?

Some medicines interact with methotrexate and could cause unexpected side effects. Always tell your doctor that you are on methotrexate when they are planning to give you any other medication. It is particularly important that you avoid a group of antibiotics called the sulphonamides which includes co-trimoxazole, and also trimethoprim. You may also need careful monitoring if you take certain antibiotics.

It is advisable to talk to your doctor or IBD nurse before taking NSAIDs (non-steroidal anti-inflammatory drugs) such as aspirin and ibuprofen because these can interact with methotrexate. These are normally not recommended for people with IBD anyway because they may make symptoms worse or trigger a flare-up. You should also tell your doctor if you are taking other anti-inflammatory drugs.

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It is also important to tell your doctor, IBD nurse or pharmacist about any other medicines you are taking or thinking of taking, including over-the-counter medicines, such as cold or flu remedies, multi-vitamins, herbal, complementary or alternative therapies.

You should always tell any other doctor or dentist treating you that you are taking methotrexate. It may help to carry a complete list of your medications with you.

CAN I HAVE IMMUNISATIONS WHILE ON METHOTREXATE?

Methotrexate suppresses the immune system, this means that it is unsafe to take certain vaccines and immunosuppressants. 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. However, you can have the 'inactivated' polio vaccine. Yearly flu injections are safe as they are not live vaccines, however, the nasal spray used for children's vaccines is live, and should not be used. The Department of Health recommends the flu vaccine and pneumococcal vaccine for people on immunosuppressants.

If anyone in your family or household needs to have a live vaccine, such as yellow fever or polio, you should check with your IBD team first. You should also check with your IBD team if you are in contact with a baby or young child undergoing a vaccination programme.

CAN I DRINK ALCOHOL WHILE TAKING METHOTREXATE?

Alcohol and methotrexate can interact and may affect your liver. Your doctor may advise you not to drink any alcohol while you are on methotrexate.

DOES METHOTREXATE AFFECT FERTILITY OR PREGNANCY?

Women who are trying to conceive or during pregnancy should not take methotrexate because it can cause birth defects or miscarriages. The evidence of risk to the foetus when the man is taking methotrexate is less clear, but the drug may affect the formation of sperm, so men as well as women are advised not to conceive while on methotrexate.

Therefore, doctors advise both men and women to use reliable contraception during treatment. Also, because traces of methotrexate can remain in body tissue for some time, couples are advised to avoid pregnancy for at least 3-6 months after stopping these drugs.

If you find you are pregnant, or decide you would like to have a child while on methotrexate, talk to your doctor about this. Women who are the partner of a man taking methotrexate should also talk to their doctor if they discover they are pregnant or wish to conceive.

WHAT ABOUT BREASTFEEDING?

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

WHAT ARE THE POSSIBLE SIDE EFFECTS OF TAKING METHOTREXATE?

As with all medicines, methotrexate can cause some unwanted side effects, although not everyone has them. The following list contains some of the possible side effects of methotrexate. For a full list of side effects, you should look at the Patient Information Leaflet which came with your methotrexate.

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I was concerned when I was prescribed methotrexate because of the possible side effects. However, it has worked very well for me, and alongside adalimumab has given me a long period of remission after surgery with no obvious side effects.

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—
Glenda, age 34
diagnosed with Crohn's Disease in 2012

- Any medication can cause an allergic reaction. If you have any sudden wheeziness, feel faint, have difficulty in breathing, or swelling of the face, lips or mouth, stop taking methotrexate and seek urgent medical attention.
- If you have any rash or itching, stop taking your methotrexate and contact your doctor immediately.
- Common side effects at the beginning of treatment with methotrexate can include feeling sick, vomiting and diarrhoea. The following suggestions may help:
 - Taking the folic acid supplement as prescribed
 - Taking your methotrexate at a different time of day, for example before you go to bed at night

If these side effects persist or are severe, talk to your doctor, who may be able to prescribe you an anti-sickness medication to take before your methotrexate. You may also be able to have your dose altered or to switch from the tablet to the injection if you are taking the oral form.

- As mentioned earlier, methotrexate affects the immune system, and can increase your risk of infections, some of which may make you seriously ill. Try to avoid close contact with people who have infections, and contact your doctor immediately if you think you have an infection – this includes having a fever, sore throat and achiness.
- In rare cases, methotrexate can affect the lungs. Tell your doctor if you become breathless, have a persistent cough, chest pain or difficulty breathing.
- Methotrexate has been known to damage the liver. Liver damage may occur with very few outward signs, but in some cases people notice a yellowing or discolouration of the skin or whites of the eyes, or develop severe itching of the skin. If this happens, you should contact your doctor immediately. Regular blood tests can show up liver damage, but special scans and a biopsy of the liver are sometimes necessary.
- Rarely, methotrexate can harm the kidneys. Kidney function should be checked along with your blood count and liver tests.

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- Methotrexate can cause bone marrow suppression, which may reduce the number of blood cells made by the bone marrow. It can cause a drop in white blood cells (that fight infection) and platelets (that assist with clotting). If you find that you bruise or bleed easily, have nose bleeds, or have blood spots or rashes on the skin, or have an infection stop taking your methotrexate and contact your doctor immediately. Methotrexate may also cause anaemia (lack of oxygen-carrying red blood cells) – your doctor should be able to tell from blood tests whether you have this. There is evidence that immunosuppressants such as methotrexate may also slightly increase the risk of other blood disorders, such as lymphoma (cancer of the lymph glands).

Methotrexate can increase the skin's sensitivity to sunlight, and the risk of developing some types of skin cancer. This can be reduced by wearing hats, light clothing and high SPF sun block.

- Some other side effects of methotrexate are listed below. Seek medical attention if you develop any of these side effects, or notice any other unusual symptoms while on methotrexate.
 - Skin rash
 - Swollen glands
 - Mouth or gum ulcers
 - Hair loss
 - Acne
 - Abdominal pain
 - Vaginal ulceration
 - Headache or dizziness or unusual sensations in the head and confusion
 - Fatigue or drowsiness
 - Blurred vision
 - Mobility problems

Overall, it is best to let your doctor or IBD team know about any new symptom you develop while on methotrexate, whenever they occur. Your IBD team should also be able to help with any questions and concerns. Regular blood tests can help to reduce the risk of developing some side effects.

This is not a complete list of side effects of methotrexate, for more information see the Patient Information Leaflet provided with your medication, or visit www.medicines.org.uk/emc.

WHO SHOULD I TALK TO IF I AM WORRIED?

If you are worried about taking methotrexate or you have any questions about your treatment, contact your doctor or IBD nurse. They should be able to help you with queries such as why it has been prescribed, what the correct dose and frequency is, what monitoring is in place, and what alternatives may be available for you.

FURTHER HELP

All our information sheets and booklets are available to download from our website: www.crohnsandcolitis.org.uk. If you would like a printed copy, please contact our Information Line – details below.

Crohn's and Colitis UK Information Line: 0300 222 5700, open Monday to Friday, 9 am to 5 pm, except Thursday open 9 am to 1 pm, and excluding English bank holidays. An answer phone and call back service operates outside these hours. You can also contact the service by email info@crohnsandcolitis.org.uk or letter (addressed to our St Albans office). Trained Information Officers provide callers with clear and balanced information on a wide range of issues relating to IBD.

Crohn's and Colitis Support: 0121 737 9931, open Monday to Friday, 1 pm to 3.30 pm and 6.30 pm to 9 pm, excluding English bank holidays. This is a confidential, supportive listening service, which is provided by trained volunteers and is available to anyone affected by IBD. These volunteers are skilled in providing emotional support to anyone who needs a safe place to talk about living with IBD.

Crohn's and Colitis UK Forum

This closed-group community on Facebook is for everyone affected by IBD. You can share your experiences and receive support from others at: www.facebook.com/groups/CCUKforum

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Methotrexate - Edition 4
Last Review - December 2015
Charity contact details updated - March 2016
Next full review planned - 2018

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ABOUT CROHN'S & COLITIS UK

We are a **national** charity established in 1979. Our aim is to improve life for anyone affected by Inflammatory Bowel Diseases. We have over 28,000 members and 50 Local groups throughout the UK. Membership starts from £15 per year with concessionary rates for anyone experiencing financial hardship or on a low income.

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