Methotrexate 2.5 mg Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Methotrexate is and what it is used for
2. What you need to know before you take Methotrexate Tablets
3. How to take Methotrexate Tablets
4. Possible side effects
5. How to store Methotrexate Tablets
6. Contents of the pack and other information

1. WHAT METHOTREXATE IS AND WHAT IT IS USED FOR

Methotrexate is an anti-metabolite medicine (medicine which affects how the body’s cells grow) and immunosuppressant (medicine which reduces the activity of the immune system).

Methotrexate is used to treat severe psoriasis (a skin disease with thickened patches of inflamed red skin, often covered by silvery scales) when other treatments are not effective, severe arthritis due to psoriasis, and rheumatoid arthritis.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE METHOTREXATE TABLETS

<table>
<thead>
<tr>
<th>Important warning about the dose of Methotrexate</th>
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</thead>
<tbody>
<tr>
<td>Take Methotrexate <strong>only once a week</strong> for the treatment of psoriasis and rheumatoid arthritis</td>
</tr>
<tr>
<td>Taking too much Methotrexate may be fatal</td>
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<tr>
<td>Please read section 3 of the leaflet very carefully</td>
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<tr>
<td>If you have any questions, please talk to your doctor or pharmacist before you take this medicine</td>
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</tbody>
</table>

Your doctor may perform several tests such as blood tests, x-rays and physical examinations before treatment with Methotrexate tablets is started, and at regular intervals during treatment.

**Do not take Methotrexate Tablets**

- if you are allergic to methotrexate, or any of the other ingredients of this medicine (listed in section 6)
- if you have significant kidney or liver problems
- if you consume excessive amounts of alcohol
• if you have been told you have (or think you have) a blood disorder such as low levels of white blood cells, red blood cells (anaemia) or platelets
• if you are pregnant or breast-feeding (see section ‘Pregnancy, breast-feeding and fertility)
• if you have any infection
• if your immune system is not working as well as it should

Tell your doctor if any of the above applies to you before this medicine is used.

**Warnings and precautions**

Acute bleeding from the lungs in patients with underlying rheumatologic disease has been reported with methotrexate. If you experience symptoms of spitting or coughing up blood you should contact your doctor immediately.

Special precautionary measures for treatment with Methotrexate
Methotrexate temporarily affects sperm and egg production, which is reversible in most cases. Methotrexate can cause miscarriage and severe birth defects. You must avoid becoming pregnant when using methotrexate and for at least six months after treatment has stopped. See also section ‘Pregnancy, breast-feeding and fertility’.

Talk to your doctor before taking Methotrexate Tablets:
• if you have a stomach ulcer or ulcerative colitis (inflammation and ulceration of the gut)
• if you have an infection
• if you have mild kidney problems
• if you have a medical condition which causes a build up of fluid in the lining of your lungs or in your abdomen (the fluid will need to be drained before methotrexate treatment is started)
• if you are to have radiotherapy (risk of tissue and bone damage may be increased)
• if you are to have any vaccinations

Special care is also needed in children, the elderly and in those who are in poor physical condition.

**Other medicines and methotrexate**
Tell your doctor if you are taking/using, have recently taken/used or might take/use any other medicines, for example:

• non-steroidal anti-inflammatory medicines e.g. ibuprofen (medicines taken for pain relief)
• aspirin or similar medicines (known as salicylates)
• medicines taken to help control rheumatism e.g. leflunomide, azathioprine and sulphasalazine
• omeprazole, esomeprazole and pantoprazole (medicines used to reduce the production of stomach acid)
• diuretics (water tablets)
• medicines used/taken for diabetes (including insulin and tablets)
• antibiotics such as penicillins, sulphonamides, co-trimoxazole, trimethoprim, tetracycline, chloramphenicol and para-aminobenzoic acid
• phenytoin (medicine often used to treat epilepsy)
• vitamin supplements containing folic acid
• probenecid (medicine used to treat gout)
• nitrous oxide (used for general anaesthesia and pain relief)
- retinoids, such as acitretin (a medicine used to treat psoriasis) or isotretinoin (used to treat severe acne)
- live virus vaccines
- mercaptopurine (medicine used in the treatment of blood cells cancer)
- theophylline (medicine used in the treatment of asthma)

**Methotrexate Tablets with alcohol**
Alcohol increases the risk of liver damage with methotrexate and it should be avoided during the full period of treatment.

**Pregnancy, breast-feeding and fertility**

**Pregnancy**
Do not use Methotrexate during pregnancy or if you are trying to become pregnant. Methotrexate can cause birth defects, harm the unborn child or cause miscarriage. It is associated with malformations of the skull, face, heart and blood vessels, brain and limbs. Therefore, it is very important that Methotrexate is not given to pregnant patients or patients planning to become pregnant. In women of child-bearing age any possibility of pregnancy must be excluded with appropriate measures, e.g. a pregnancy test before starting treatment. You must avoid becoming pregnant whilst taking methotrexate and for at least 6 months after treatment is stopped by using reliable contraception throughout this time (see also section ‘Warnings and precautions’).

If you do become pregnant during treatment or suspect you might be pregnant, speak to your doctor as soon as possible. You should be offered advice regarding the risk of harmful effects on the child through treatment.

If you wish to become pregnant you should consult your doctor, who may refer you for specialist advice before the planned start of treatment.

**Male fertility**
The available evidence does not indicate an increased risk of malformations or miscarriage if the father takes methotrexate less than 30 mg/week. However, a risk cannot be completely excluded. Methotrexate may be genotoxic. This means that the medicine may cause genetic mutation. Methotrexate can affect sperm production with the potential to cause birth defects. Therefore, you should avoid fathering a child or donating semen whilst taking methotrexate and for at least 6 months after treatment is stopped.

If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Mothers must not breast-feed whilst treatment with methotrexate is ongoing.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**
Do not drive or use machines if you experience any side effect (e.g. dizziness, drowsiness or blurred vision) which may lessen your ability to do so.

**Methotrexate Tablets contain lactose**
These tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
3. **HOW TO TAKE METHOTREXATE TABLETS**

Always take these tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed whole with a drink of water whilst sitting upright or standing.

**Recommended Dose**

*Rheumatoid arthritis:*
Take methotrexate tablets **only once a week**. The dose usually starts at 7.5 to 15 mg per week but may rise to 20 mg per week. The dose may be given all at once, or it can be split into 3 doses at 12 hourly intervals over 24 hours.

*Psoriasis:*
Take methotrexate tablets **only once a week**. The dose is usually between 5 to 25 mg per week. The dose may be given all at once, or it can be split into 3 doses at 12 hourly intervals over 24 hours.

Before treatment is started your doctor may carry out blood tests to check the levels of cells in your blood, and also to check how well your kidneys and liver are working. You may also have a chest X-ray. Further tests may also be done during and after treatment. Do not miss appointments for blood tests.

**Use in children**
This medicine can be used to treat children with severe psoriasis, but should not be used in those under 3 years of age.

**If you take more Methotrexate Tablets than you should**
See your doctor or go to a hospital Accident and Emergency (Casualty) Department at once. Take your medicine container and show it to the doctor or nurse who treats you.

**If you forget to take Methotrexate Tablets**
Do not take a double dose to make up for forgotten tablets. Ask your doctor for advice.

4. **POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them. However, Methotrexate is a very toxic medicine and some patients have died, or become very ill whilst being treated with it. During treatment you should watch for any side effects and report them to your doctor.

**If any of the following happen, tell your doctor immediately:**
- severe allergic reaction - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint
- inflammation of the lung with breathlessness – you may develop a persistent cough, experience pain or difficulty breathing, or become breathless
- spitting or coughing blood
- symptoms of an infection e.g. fever, chills, achiness, sore throat
- unexpected bleeding e.g. bleeding gums, blood in the urine or in vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins)
- black tarry stools
- a sore mouth, particularly if you have a number of ulcers or blisters inside of the mouth or on the tongue
- skin rashes or blistering to the surfaces of the eyes, nose, vagina or anus (back passage)
- inflammation of the vagina
- diarrhoea
- abdominal pain, fatty stools, vomiting
- chest pain (which may be due to heart or lung problems)

These are serious side effects. You may need urgent medical attention.

If any of the following happen, tell your doctor as soon as possible:
- low blood pressure (you may feel faint)
- fits
- blurred vision or eye infection (conjunctivitis)
- dizziness
- difficulty with speech
- muscle weakness
- diabetes (you may feel the need to drink more than usual)
- abnormally easily broken bones (osteoporosis)
- vasculitis (pain or redness of the blood vessels)
- itching or the appearance of lightened patches on the skin, bruises, boils and increased sensitivity to sunlight
- jaundice (yellowing of the skin)
- pain in the stomach, loins or abdomen
- cystitis (you may need to pass urine more often than usual, which may be painful)
- eye irritation
- headaches
- unusual sensations in the head
- drowsiness
- reduced appetite, feeling or being sick
- irregular periods in women (periods may stop completely)
- loss of libido/impotence
- hair loss
- effects on learning and memory
- ringing in the ears
- joint and muscle pain
- blood clot which causes pain, swelling or redness (cerebral, deep vein, retinal vein or arterial vein)
- mood alterations
- inflammation of the lungs, which causes breathlessness, cough and raised temperature, pneumonia
- shingles (Herpes Zoster)
- bleeding from the lungs (frequency not known)
- lymphoproliferative disorders (excessive growth of white blood cells) (frequency very rare)
- bone damage in the jaw (secondary to excessive growth of white blood cells) (frequency not known)

Methotrexate may lead to problems with your blood, liver and kidneys. Your doctor will take blood samples to check for these problems and may ask you to have a small sample of your liver taken for testing (liver biopsy).
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Effects on fertility
Treatment with methotrexate may reduce fertility in men and women. Fertility is thought to go back to normal after methotrexate treatment is stopped. Tell your doctor if you have concerns.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE METHOTREXATE TABLETS

Keep this medicine out of the sight and reach of children.

Expire
Do not use this medicine after the expiry date which is stated on the label and carton after ‘EXP’. Where only a month and year is stated, the expiry date refers to the last day of that month.

Storage
This medicine does not require any special storage conditions.

Disposal
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Methotrexate Tablets contain
The active substance is methotrexate. Each tablet contains 2.5 milligrams (mg) of methotrexate.

The other ingredients are maize starch, lactose, pre-gelatinized starch, polysorbate 80, microcrystalline cellulose and magnesium stearate.

What Methotrexate Tablets look like and contents of the pack
Methotrexate 2.5 mg Tablets are round, yellow and marked ‘M 2.5’ on one side.

Methotrexate 2.5 mg Tablets are supplied in plastic bottles containing 100 tablets.

Marketing authorisation holder and manufacturer
Hospira UK Limited, Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, UK

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