

3. How to take Methotrexate Tablets

Important warning about the dose of Methotrexate Tablets:

Take Methotrexate Tablets **only once a week** for the treatment of rheumatoid arthritis and psoriasis. Taking too much of Methotrexate Tablets may be fatal. Please read section 3 of this leaflet very carefully. If you have any questions, please talk to your doctor or pharmacist before you take this medicine.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Alcohol should be avoided while receiving methotrexate. The usual dose is:

The recommended dose is:

Dose in rheumatoid arthritis and psoriasis:
Take Methotrexate Tablets only once a week.

Dosage for rheumatoid arthritis:

You will usually take your tablets once a week on the same day each week. The dose will normally be between 7.5 and 20mg. However, this may be changed depending upon your response to treatment.

Elderly

Elderly patients may need smaller doses of methotrexate.

Children

Not recommended for use in children.

Dosage for psoriasis:

Adults: For severe psoriasis, the usual dose is 10 mg to 25 mg by mouth, once weekly. This should be adjusted according to your response to treatment and side effects.

Elderly: No dosage adjustment required.

Children: Not recommended for use in children.

These doses may be adjusted if you are receiving other medication. Your doctor will decide the correct dose for you, if you want more information you should ask your doctor.

If you have the impression that the effect of Methotrexate Tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more Methotrexate Tablets than you should

This medicine is usually taken once a week. If you take more of the medicine than you should, a physician or nearest hospital casualty department must be contacted immediately. Take your medicine package with you if you go to a doctor or hospital.

Overdose symptoms may include easy bruising or bleeding, unusual weakness, mouth sores, nausea, vomiting, black or bloody stools, coughing up blood or vomit that looks like coffee grounds, and decreased urinating.

Inappropriate intake resulting in overdose can sometimes lead to death. The antidote in case of an overdose is calcium folinate.

If you forget to take Methotrexate Tablets

Take the forgotten dose as soon as you remember if this is within two days. However, if you have missed a dose by more than two days, please contact your doctor for advice. Do not take a double dose to make up for a forgotten dose.

If you stop taking Methotrexate Tablets

Do not stop taking the tablets unless your doctor tells you to. If you have any further questions on how to take this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Methotrexate Tablets 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.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, these symptoms can be serious.

- **Severe skin rash that causes blistering** (this can affect the mouth and tongue). These may be signs of a condition known as Stevens Johnson Syndrome. Your doctor will stop your treatment in these cases.
- **Persistent cough, pain or difficulty breathing, or becoming breathless**, methotrexate can cause diseases of the lungs e.g. fluid in lungs.
- **Spitting or coughing blood**; this has been reported for methotrexate used in patients with underlying rheumatologic disease.
- **Skin rash and fever with swollen glands**, particularly in the first two months of treatment, as these may be signs of a hypersensitivity reaction.
- **Sore throat, fever, chills, or achiness**, methotrexate can make you more likely to catch infections.
- **Severe allergic reaction (anaphylactic reaction)**, although very rare you may experience a sudden itchy skin rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), wheeze, and you may feel you are going to faint. If this happens you should seek medical attention immediately.

Other side-effects that may occur are:

- Severe mouth ulcers and ulcers of the gut
- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- Reduction in blood platelets which increases risk of bleeding or bruising
- Lung infection (Pneumonia)
- Drowsiness
- Severe skin reaction
- Inflammation of vessels, often with skin rash
- Itchy skin
- Shingles (Herpes Zoster)
- Ringing in the ears
- Abdominal pain
- Indigestion
- Convulsions
- Loss of coordination
- Asthma
- Confusion
- Liver damage (seen as yellowing of the skin and whites of the eye)
- Liver failure
- Kidney damage
- Low levels of white cell count (leukopenia) and red blood cells and cells that clot blood
- Infection, reduced resistance to infection
- Abnormal red blood cell function
- Lung damage/scarred
- Build-up of excess fluid in the lung
- Build-up of fluid or excess fluid in the double layer around the heart
- Abnormal low blood pressure
- Inability to move
- Inability to move in one half of the body
- Dizziness
- Headaches, Blurred vision
- Difficulty sleeping
- Raised blood sugar levels (diabetes mellitus)
- Change in sense of taste
- Loss of ability to speak or understand speech
- Impaired vision
- Brittle bones

- Muscular pain
- Slow thought process
- Mood alteration
- Black or tarry stools
- Skin ulcers and erosions of inflamed areas, in psoriasis patients
- Damaged skin becomes inflamed on re-exposure to radiation and sunlight
- Reduced ability to become pregnant and reduced ability to father children
- Inflammation of the vagina
- Vaginal bleeding
- Menstrual disorders
- Blood in the urine
- Raised liver enzymes
- Weakening or softening of bones
- Unusual sensations in the head
- Anorexia (eating disorders)
- Loss of interest in, or inability to have sex
- Stomach pains and soreness of the mouth, throat and lips
- Inflamed blood vessels
- Feeling sick, being sick and/or diarrhoea, decreased absorption from intestines
- Irritation or swelling of the vaginal tissues
- Vaginal ulcers
- Pain or difficulty in passing urine
- The need to pass urine more often than usual
- Ulcers in urinary bladder
- Joint and muscle pain
- Chills and fever
- Changes in skin and nail colouration
- Bacteria or fungal infection of hand and feet
- Hair loss
- Red spots on the skin, skin lesions, acne, boils
- Redness and shedding of skin (frequency not known)
- Itchiness and rash
- Sensitivity to light
- Eye irritation
- Tiredness and lack of energy
- General feeling of illness
- Other metabolic changes
- Nose bleed (frequency not known)
- Bleeding from the lungs (frequency not known) – this has been reported for methotrexate used in patients with underlying rheumatologic disease
- 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)
- Sensation of numbness or tingling / having less sensitivity to stimulation than normal (frequency very rare)
- Swelling (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).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 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. Accidental ingestion can be lethal for children.

This medicinal product does not require any special temperature storage conditions.

Keep the blister in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.

Anyone handling methotrexate should wash their hands after administering a dose. To decrease the risk of exposure, parents and care givers should wear disposable gloves when handling methotrexate.

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

Each tablet contains 2.5 mg of the active ingredient methotrexate.

The other ingredients are anhydrous calcium hydrogen phosphate, lactose monohydrate, sodium starch glycolate, microcrystalline cellulose, purified talc and magnesium stearate.

What Methotrexate Tablets look like and contents of the pack

Methotrexate Tablets are yellow coloured, circular, biconvex, uncoated tablets plain on both sides.

Methotrexate 2.5 mg Tablets are available in blister packs of 7, 10, 14, 20, 24, 28, 30, 56, 60, 84, 90, 100 and 112 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Morningside Healthcare Ltd.
Unit C, Harcourt Way
Leicester LE19 1WP
United Kingdom

Manufacturer

Morningside Pharmaceuticals Ltd.
5 Pavilion Way, Loughborough, LE11 5GW
United Kingdom

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Manufacturer

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