

DBL™ Methotrexate Tablets

methotrexate (meth-o-TREX-ate)

Consumer Medicine Information

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What is in this leaflet

This leaflet answers some common questions about methotrexate.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What DBL™ Methotrexate Tablets is used for

This medicine is used to treat:

- severe psoriasis (a skin condition)
- severe rheumatoid arthritis (a chronic inflammatory condition)
- some types of cancers.

The medicine contains methotrexate, which belongs to a family of medicines called antimetabolites. It may also be called a chemotherapy medicine.

The medicine works by blocking an enzyme needed by the body cells to live. This interferes with the growth of some cells that are growing rapidly in psoriasis and cancer. In rheumatoid arthritis, this medicine reduces the overactivity of the immune system leading to less pain, swelling and damage to the joints.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is only available with a doctor's prescription.

Before you take DBL™ Methotrexate Tablets

When you must not take it

Do not take the medicine if you have an allergy to:

- any medicine containing methotrexate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take the medicine if you have:

- severe kidney problems
- lowered immunity due to diseases such as HIV/AIDS or due to other treatments
- blood disorders, including anaemia (low iron in the blood) and reduced number of red or white blood cells or platelets
- bone marrow disease
- liver disease
- poor nutritional status
- stomach ulcers
- ulcerative colitis, inflammation of the bowel
- an infection
- an alcohol dependence (alcoholism).

Do not take the medicine if you are pregnant or trying to become pregnant.

Methotrexate is not recommended for use during pregnancy. If there is any need to consider methotrexate during

your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of using it.

Do not take the medicine if your partner is trying to become pregnant.

The medicine may cause birth defects if either you or your partner is taking it.

Do not take the medicine if you are breastfeeding.

It passes into the breast milk and may affect you baby.

Do not take this medicine if you are taking acitretin or etretinate, a medicine used to treat psoriasis and other skin conditions.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- lung problems
- diabetes
- folate deficiency.

Your doctor may do tests to check your blood, liver and kidneys.

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

Tell your doctor if you or your partner becomes pregnant while you are taking or just after you stop taking the medicine.

The medicine may cause birth defects if either the male or female partner is taking it. Use a proven method of birth control, such as the

contraceptive pill or a condom, while taking the medicine and for at least 12 weeks after you stop treatment.

If you are taking this medicine to treat cancer, tell your doctor if you have or have had any of the following medical conditions:

- any blood disorders, or conditions that cause a reduced number of red blood cells, white blood cells, or platelets
- bone marrow disease
- anaemia (low iron in the blood)
- stomach ulcers (peptic ulcer disease)
- liver problems
- ulcerative colitis, a condition where your colon (large bowel) is inflamed and has ulcers.

If you have not told your doctor about any of the above, tell them before you start using the medicine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

If your doctor tells you to take folic acid, do not take it on the same day as methotrexate.

Folic acid is included in many multi-vitamin preparations. Folic acid and methotrexate interact with each other if you take them on the same day of the week. It is all right to take these medicines on another day of the week.

Some other medicines and methotrexate may interfere with each other. These include:

- aspirin and other pain relievers or anti-inflammatory medicines
- some antibiotics, including tetracyclines, penicillins, sulphonamides, trimethoprim and chloramphenicol
- phenytoin, a medicine used to treat epilepsy
- sulfonylurea medicines used to treat diabetes
- allopurinol and probenecid, medicines used to treat gout

- pyrimethamine, a medicine used to prevent malaria
- cholestyramine, a medicine used to lower blood cholesterol levels
- theophylline, a medicine used to treat asthma
- azathioprine, a medicine used to prevent transplant organ rejection
- amiodarone, a medicine used to treat heart disorders
- leflunomide, a medicine used to treat rheumatoid arthritis
- sulfasalazine, a medicine used to treat Crohn's disease, ulcerative colitis and rheumatoid arthritis
- retinoids (acitretin or e-tretinate), medicines used to treat skin conditions
- some medicines used to treat cancers (such as cisplatin, asparaginase, mercaptopurine)
- methoxsalen, a medicine used with UV light for skin conditions, such as severe psoriasis
- proton pump inhibitors, such as omeprazole esomeprazole and, pantoprazole
- nitrous oxide anaesthesia.

These medicines may be affected by methotrexate, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Tell your doctor if you are due to receive any vaccinations.

You should not receive certain vaccinations while being treated with methotrexate.

Your doctor and pharmacist may have more information on medicines/vaccinations to be careful with or avoid while you are being treated with methotrexate.

Tell your doctor if you drink alcohol.

Alcohol may affect how well the methotrexate works. Your doctor has more information on medicines to be careful with or avoid while using this medicine.

Talk to your doctor if you are not sure whether you should be taking this medicine.

How to take DBL™ Methotrexate Tablets

Important Dosage Instructions

Always read the pharmacist's label to check the exact dose and how often to take it.

The dose depends on the condition this medicine is being used for.

Make sure that you understand how often your doctor wants you to take methotrexate to treat your medical condition.

There are different doses for rheumatoid arthritis or psoriasis, and cancer. It is important not to take methotrexate more often or in higher doses than your doctor has prescribed for your condition. Overdoses of methotrexate may cause serious illness or death.

If you are unsure about the dosage, ask your doctor or pharmacist.

Never take it more often than your doctor has told you to.

Your doctor will tell you how much to take and when to take it.

How to take it

Do not crush or chew the tablets.

Swallow the tablets whole with a full glass of water.

RHEUMATOID ARTHRITIS AND PSORIASIS

Take the tablets once a week on the same day each week for rheumatoid arthritis and psoriasis.

Only take your dose on the day agreed with your doctor or pharmacist.

CANCER

For cancer, take the tablets at the same time of day and only on the days specified by your doctor.

Taking the tablets at the same time of day will have the best effect. It will also help you to remember when to take the medicine.

How long to take it

Continue taking the medicine for as long as your doctor tells you to. Ask your doctor if you are not sure how long to take it.

If you forget to take it

If you forget to take a dose, ask your doctor or pharmacist for advice.

Never take a double dose to make up for the dose that you missed. This may increase the chance of you getting unwanted side effects.

If you find it hard to remember how to take the tablets, ask your doctor or pharmacist for help.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Methotrexate. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep all of your doctor's appointments so that your progress can be checked.

You will need to have regular blood and urine tests. Regular blood tests will show any abnormal effects of methotrexate on the blood cells and the liver. As you may not get symptoms of these problems you must have regular blood checks. Your doctor may also want you to have some other tests.

Use a proven method of birth control, such as the contraceptive pill or a condom, while taking the medicine and for at least 12 weeks after stopping treatment.

The medicine may cause birth defects if either you or your partner is taking it.

If you become pregnant while using this medicine, tell your doctor immediately.

Tell any other doctors, dentists, or pharmacists who treat you that you are taking this medicine.

If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are taking this medicine.

If you are going to have surgery, tell the surgeon, anaesthetist or dentist that you are using this medicine.

It may affect other medicines used during surgery.

Things you must not do

Do not go out in the sun if possible.

If you need to be in the sun, use a 30+ sunscreen and wear a hat and shirt to protect your skin from the sun.

This medicine may make your skin more sensitive to sunlight. This means your skin may burn more quickly than usual. Some signs are:

- redness
- itching
- swelling
- blistering
- rash.

Do not use sun lamps.

Do not drink alcohol while taking the medicine.

Alcohol may increase the side effects of the medicine.

Do not stop taking the medicine, or change the dose, unless your doctor tells you to.

Do not start to take any other medicine before talking to your doctor or pharmacist.

Do not use this medicine to treat any other conditions unless your doctor tells you to.

Do not allow pregnant women to handle this medicine.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how the medicine affects you.

It may cause dizziness, drowsiness or tiredness in some people. Make sure you know how you react to the medicine before you drive a car, operate machinery, or do anything that could be dangerous.

Carers and other people who handle the tablets should wear disposable gloves to avoid direct contact with the tablets.

Pregnant women should not handle the medicine at all.

This medicine may cause harm to the unborn baby.

Because this medicine can reduce the ability of your immune system to fight infections, try to reduce the risk of infection. Maintain good hygiene. Some ways you can do this are:

- avoid people with infections if possible
- be careful when using a tooth brush, toothpick or dental floss
- be careful not to cut yourself
- avoid activities where you might be injured or bruised
- wear disposable gloves when cleaning, especially when cleaning up body fluid or waste

- dispose of gloves, rags or other items safely in a sealed plastic bag.

Side effects

Be aware that taking more than the exact prescribed dose can be dangerous.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using this medicine.

This medicine may have unwanted side effects in a few people. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- upset stomach, stomach pain, vomiting, nausea, loss of appetite
- mild dizziness
- mild chills
- mild headaches
- hair loss
- mood changes or confusion
- ringing in the ears
- sore eyes
- increased sensitivity to sunlight
- unexplained weight loss or loss of appetite
- tiredness or drowsiness
- weakness
- unusual or excessive thirst
- inflamed gums or sore mouth
- impotence or loss of interest in sex
- painful muscles and joints
- changes in menstrual cycle or unusual vaginal discharge.

The above list includes side effects that are usually mild or only last for a short time.

Tell your doctor as soon as possible if you notice any of the following:

- vomiting
- back pain
- stiff neck
- headaches, shortness of breath when exercising, dizziness, looking pale - signs of anaemia
- bleeding or bruising more easily than usual
- seizures, fits or convulsions
- muscle cramps, spasms, weakness or paralysis
- blurred vision, short term blindness
- difficulty speaking, writing or understanding language.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- signs of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body
- skin disorders, such as rash, ulceration or hives; itchy skin
- swollen glands (lymph nodes)
- persistent diarrhoea
- mouth ulcers
- chest pain
- dry non-productive cough
- swelling of the face, lips, tongue or other parts of the body (eg hands ankles or feet)
- fever, sore throat or chills - signs of infection
- pain or difficulty urinating, lower back or side pain - signs of a possible kidney disorder
- yellowing of the skin or eyes, light coloured bowel motions, dark coloured urine, generally feeling unwell - signs of possible liver disease
- blood in urine or bowel motions, black tarry bowel motions, black vomit, pin-point red spots on the

skin - signs of internal bleeding or other bleeding disorders.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects can only be found when your doctor does blood, urine or other tests from time to time to check your progress.

Tell your doctor immediately if you notice any of the side effects even after you have finished your treatment.

Some side effects of methotrexate may occur after you stop taking it.

After using DBL™ Methotrexate Tablets

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store methotrexate or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

DBL™ Methotrexate Tablets are yellow, round, biconvex tablets, unscored, engraved "M 2.5" on one side and plain on the other side. They are available in bottles of 30 tablets.

Ingredients

DBL™ Methotrexate Tablets contain 2.5 mg of methotrexate as the active ingredient. They also contain:

- lactose
- maize starch
- pregelatinised maize starch
- polysorbate 80
- cellulose - microcrystalline
- magnesium stearate.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
58 Richard Pearse Drive
Airport Oaks, Mangere 2022
Auckland
New Zealand

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