

METHOBLASTIN®

Methotrexate

Consumer Medicine Information

WARNING: The usual dose is once weekly. Check your dose and frequency with your doctor or pharmacist if you are unsure of your dose. It is important NOT to take METHOBLASTIN more often or in higher doses than your doctor has prescribed. Overdoses of methotrexate may cause serious illness or death.

What is in this leaflet

Please read this leaflet carefully before you start taking METHOBLASTIN.

This leaflet answers some common questions about METHOBLASTIN. It does not contain all the available information and 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 taking METHOBLASTIN against the expected benefits it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What METHOBLASTIN is used for

METHOBLASTIN is used to treat severe psoriasis (a skin condition) and severe rheumatoid arthritis. It is only used to treat these conditions if other treatments have not worked.

It is also used to treat 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's 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 METHOBLASTIN

When you must not take it

Do not take METHOBLASTIN 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
- severe liver disease
- 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.

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 your baby.

Do not take this medicine if you are taking acitretin or etretinate,

medicines used to treat psoriasis and other skin conditions.

Do not use METHOBLASTIN 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
- liver problems, including hepatitis B or hepatitis C
- lung problems
- diabetes
- folate deficiency
- abnormal cell count
- lactose or galactose intolerance (METHOBLASTIN contain lactose).

Tell your doctor if you have a family history of liver problems.

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 6 months after you stop treatment.

Swelling or infection of the brain has been reported by some cancer patients taking METHOBLASTIN and may have the same effect on patients taking METHOBLASTIN for other conditions.

Male patients should consider sperm preservation before starting METHOBLASTIN therapy.

Treatment may cause irreversible damage to sperm production.

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 before you have any immunisations.

Some vaccines must not be given while you receive treatment with METHOBLASTIN.

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.

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

- aspirin and other pain relievers or anti-inflammatory medicines
- some antibiotics
- phenytoin, a medicine used to treat epilepsy
- sulfonylurea medicines used to treat diabetes
- diuretics, also known as fluid tablets
- probenecid, a medicine 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
- amiodarone, a medicine used to treat heart disorders
- azathioprine, a medicine used to prevent transplant organ rejection

- cyclosporin, a medicine used to prevent transplant organ rejection, and to treat rheumatoid arthritis, psoriasis, dermatitis.
- leflunomide, a medicine used to treat rheumatoid arthritis
- sulfasalazine, a medicine used to treat Crohn's disease, ulcerative colitis and rheumatoid arthritis
- retinoids, medicines used to treat skin conditions, such as acitretin
- methoxsalen, a medicine used with UV light (PUVA therapy) for skin conditions, such as severe psoriasis
- folic acid, a vitamin that may be present in multi-vitamin preparations (take your folic acid preparation on another day of the week, separate from METHOBLASTIN)
- some medicines used to treat cancers such as mercaptopurine, cisplatin, asparaginase
- vaccines
- nitrous oxide
- packed red blood cells, blood transfusions
- proton pump inhibitor medicines which are used to treat stomach ulcers and reflux, such as omeprazole, pantoprazole.

Tell your doctor if you drink alcohol.

Alcohol may affect how well METHOBLASTIN 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.

Taking METHOBLASTIN

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 METHOBLASTIN to treat your condition.

There are different doses for rheumatoid arthritis or psoriasis, and cancer. It is important not to take METHOBLASTIN 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 your METHOBLASTIN

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

Never take a double dose to make up for the dose you missed.

If you have any trouble remembering when to take your tablets, ask your pharmacist for help.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 131 126), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much METHOBLASTIN. Do this even if there are no signs of discomfort or poisoning.

You will need urgent medical attention.

While you are taking METHOBLASTIN

Things you must do

Tell your doctor or pharmacist if you are taking any other medicine.

Check your tablets very carefully each time you collect them from your pharmacist.

METHOBLASTIN are made in two strengths. You should check to make sure that you are given the correct strength.

Wash your hands immediately after taking the medicine.

Drink plenty of water on the day you take the medicine.

The recommended daily intake is 8 glasses per day.

Tell your doctor immediately if you are spitting or coughing up blood when using METHOBLASTIN.

Some patients have reported acute bleeding in the lungs when using METHOBLASTIN to treat rheumatoid arthritis and other related diseases.

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 METHOBLASTIN 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 6 months 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 about to be given an immunisation, remind your doctor 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 handle this medicine if you are pregnant.

This medicine may cause harm to the unborn baby.

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 contact with the skin.

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:

- upset stomach, stomach pain, vomiting, nausea
- loss of appetite
- headache, dizziness
- hair loss
- brown/black discolouration on the nails, nail infection
- dark or light patches on the skin

- mood changes, depression or confusion
- ringing in the ears
- sore eyes, blurred vision
- increased sensitivity to sunlight
- unexplained weight loss
- tiredness or drowsiness
- weakness, difficulty moving one side of the body
- unusual or excessive thirst
- breast enlargement
- impotence or loss of interest in sex
- painful muscles and joints
- changes in menstrual cycle or unusual vaginal discharge
- feeling irritable or moody.

The above list includes side effects that are usually mild.

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

- headaches, shortness of breath when exercising, dizziness, looking pale - signs of anaemia
- bleeding or bruising more easily than usual
- seizures, fits or convulsions
- 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:

- persistent diarrhoea
- skin disorders, such as redness/ rash, ulceration, blistering; hives or itchy skin
- signs of infection, including fever and chills
- chest discomfort or pain. Chest pain may be experienced radiating to your neck, shoulders or back

- dry, non-productive cough
- shortness of breath, wheezing, or difficulty breathing
- spitting or coughing blood
- weakness or lightheadedness
- swelling of the face, lips, tongue or other parts of the body
- mouth ulcers, sore throat, fever 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
- swelling and pain in the legs - signs of a blood clot in the leg
- fast heart rate, shortness of breath, sharp chest pain that worsens with deep breathing, or coughing up blood - signs of a blood clot in the lungs.

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

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.

The side effects from METHOBLASTIN may occur after you stop taking it.

After taking METHOBLASTIN

Storage

Do not store METHOBLASTIN 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 METHOBLASTIN look like

METHOBLASTIN 2.5 mg tablets are round, pale yellow tablets marked with "M 2.5" on one side. Available in packs of 30 tablets.

METHOBLASTIN 10 mg tablets are capsule shaped, pale yellow tablets marked with "M10" on the same side as the score line. Available in packs of 15 and 50 tablets.

Ingredients

The active ingredient is methotrexate.

The inactive ingredient is lactose monohydrate, maize starch, pregelatinised maize starch, polysorbate 80, microcrystalline cellulose, magnesium stearate.

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

Supplier

Pfizer Australia Pty Ltd
Sydney, NSW.

Toll Free number: 1800 675 229.

www.pfizer.com.au

Australian Registration Numbers

2.5 mg: AUST R 15418.

10 mg: AUST R 15417.

This leaflet was revised in April 2019.

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