

METHOBLASTIN® PFS (Methotrexate)

methotrexate (meth-o-TREX-ate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about METHOBLASTIN® PFS. 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 taking METHOBLASTIN® PFS against the benefits they expect 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® PFS is used for

This medicine is used to treat:

- severe psoriasis (a skin condition)
- severe rheumatoid arthritis (a chronic inflammatory condition)

when these conditions do not improve with other medicines.

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. 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/is not addictive.

It is only available with a doctor's prescription.

Before you use METHOBLASTIN® PFS

When you must not use it

Do not use 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 use the medicine if you have:

- severe kidney problems
- a problem with your immune system such as severe or repeated infections, e.g. tuberculosis or HIV/AIDS any blood disorders, or conditions which causes a reduced number of red or white blood cells or platelets

- are receiving radiotherapy e.g. X-rays, ultraviolet radiotherapy
- bone marrow disease
- liver disease
- poor nutritional status
- stomach ulcers
- ulcerative colitis, inflammation of the bowel
- an infection
- an alcohol dependence (alcoholism).

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

Do not use live vaccine while you are using METHOBLASTIN® PFS

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

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

Do not use the medicine if you are breastfeeding.

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.

Do not take this medicine/it 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 use it

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

Tell your doctor if you plan to become pregnant.

METHOBLASTIN® PFS is not recommended for use during pregnancy. The medicine may cause birth defects if either you or your partner is taking it. Use a reliable 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. Your doctor will discuss with you what forms of contraception are suitable and when it is safe to stop using contraception if you wish to do so.

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.

Your carer should not be a person who is pregnant, or intends to become pregnant.

Tell your doctor if you are breastfeeding or plan to breastfeed.

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

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

- kidney problems

- lung problems
- liver problems
- fluid or swelling in your abdomen or stomach
- blood disorders
- diabetes
- folate deficiency.
- cancer

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.

Tell your doctor if you will have a friend or relative care for you or help to give you the METHOBLASTIN® PFS

Your carer will also need to take some precautions, such as wearing of gloves, when handling the injection.

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

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 or pharmacist 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 or treatments and methotrexate may interfere with each other. These include:

- aspirin and other pain relievers or anti-inflammatory medicines
- non-steroidal anti-inflammatory drugs, used to help with pain relief, such as azapropazone, diclofenac, indomethacin and ketoprofen
- 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 asparaginase and mercaptopurine)
- methoxsalen, a medicine used with UV light for the treatment of skin conditions, such as severe psoriasis
- proton pump inhibitors, such as omeprazole, esomeprazole or pantoprazole
- nitrous oxide anaesthesia
- radiation e.g. X-rays, radiotherapy

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 use METHOBLASTIN® PFS

Important Dosage Instructions

Always read the pharmacist's label to check the exact dose and how often to use 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 use methotrexate to treat your medical condition.

There are different doses for rheumatoid arthritis or psoriasis. It is important not to use methotrexate more often or in higher doses than your doctor has prescribed for your condition. You should only use one dose of METHOBLASTIN® PFS per week as directed by your doctor. Overdoses of methotrexate may cause serious illness or death.

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

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

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

Instructions for handling

The following protective recommendations are given due to the toxic nature of this substance:

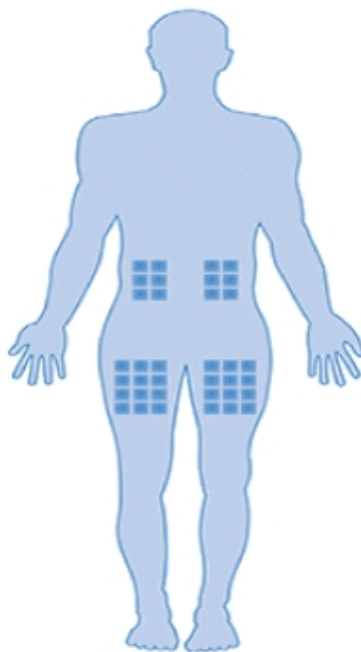
- personnel should be trained in good handling technique
- pregnant staff should be excluded from working with this drug

- **it is important that you and your caregiver wear disposable gloves when handling methotrexate injection**
- Accidental contact with the skin or eyes should be treated immediately with copious lavage with water or sodium bicarbonate solution; medical attention should be sought.

How to use it

Your doctor or nurse will show you or your carer how to use the METHOBLASTIN® PFS.

Do not inject the methotrexate until you are confident you can do it on your own. METHOBLASTIN® PFS should be given subcutaneously (under the skin) around the tummy area or in the thigh (see figure below).



Give the injection a few centimetres away from the belly button area.

Each week, you should use METHOBLASTIN® PFS in a different area.

Alternate between tummy and thigh, and between right and left sides.

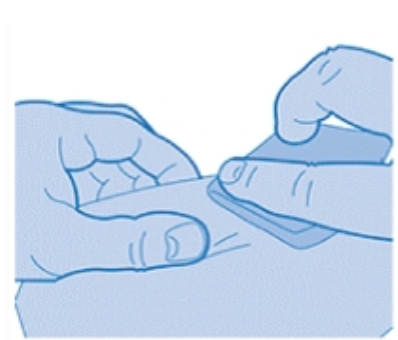
Never inject into skin that is tender, bruised, red, hard, scarred or where you have stretch marks, psoriatic patches or lesions.

If you weigh more than 100kg, you should only inject METHOBLASTIN® PFS in your upper thigh and NOT in your abdomen.

This is the best place for the injection.

Injecting the solution:

1. Remove the pre-filled syringe from the packaging at room temperature.
2. Warm the syringe gently in your hands before injecting to avoid pain.
3. Choose an injection site and disinfect it with the alcohol swab provided. Allow at least 60 seconds for the alcohol to dry.



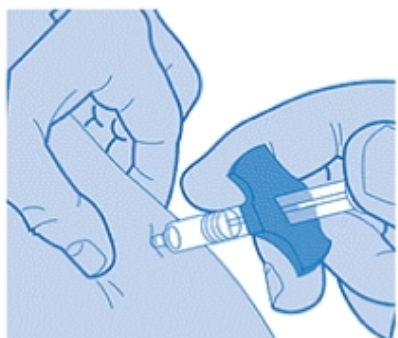
4. Carefully remove the protective plastic cap by pulling it straight off the syringe. If the cap is very stiff, turn it slightly with a pulling movement. Important: Do not touch the needle of the pre-filled syringe.



5. Using two fingers, pinch up a fold of skin and quickly insert the needle into the skin at a 90-degree angle.



6. Insert the needle fully into the fold of skin. Slowly push the plunger down completely to inject the liquid underneath your skin. Hold the skin securely until the injection is completed. Carefully pull the needle straight out.



If you are given the injection by a carer, they should wear protective clothing and ensure they wash their hands before and after giving the injection.

You should use or be given the entire dose in the syringe.

Use METHOBLASTIN® PFS once a week on the same day each week for rheumatoid arthritis and psoriasis.

Only use your injection on the day agreed with your doctor or pharmacist.

Do not use METHOBLASTIN® PFS every day.

If you have any questions about how to use the injection, speak to your doctor or a nurse.

How long to use 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 use it.

If you forget to use it

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

Never use 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 give the injection, ask your doctor or nurse for help.

If you use 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 given you too much Methotrexate. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using
METHOBLASTIN® PFS

Things you must do

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

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

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. Inadequate fluid intake can increase the side effects of the medicine. 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.

Both you and your partner must use a reliable 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. Your doctor will discuss with you what forms of contraception are suitable and when it is safe to stop using contraception if you wish to do so.

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 and increase risk of skin cancer (non-melanoma and melanoma). 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 injection should wear disposable gloves to avoid direct contact with the injection fluid.

Pregnant women should not handle the medicine at all.

This medicine may cause harm to the unborn baby.

Be careful not to drip the solution on any surfaces.

If you do, wipe up the area with paper towels and throw them into the 'Sharps Bin'. Clean the area with lots of soap and water.

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), mouth ulcers, sore throat and fever
- persistent diarrhoea
- chest pain
- dry non-productive cough
- swelling of the face, lips, tongue or other parts of the body (e.g. 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 METHOBLASTIN® PFS

Storage

Keep METHOBLASTIN® PFS in the pack until it is time to use it.

Keep METHOBLASTIN® PFS in a cool dry place where the temperature stays below 25°C.

Do not store METHOBLASTIN® PFS 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.

Only use each syringe once. Do not keep the syringe after it has been used, even if you don't use all of the medicine.

If any of the medicine is left over, you must still throw it away. It cannot be stored in the fridge for another day.

Disposal

After using METHOBLASTIN® PFS, throw the used syringe into a 'Sharps Bin'.

The used syringe should be thrown into a special plastic bin (Sharps Bin) that you can get from your pharmacy or hospital.

Do not throw the used syringe into your normal rubbish bin.

Once the 'Sharps Bin' is full, return it to the pharmacy or hospital for disposal. They will dispose of it properly.

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

METHOBLASTIN® PFS comes in a prefilled syringe with a needle.

Ingredients

METHOBLASTIN® PFS contains 25 mg of methotrexate, as the active ingredient, in each millilitre of injection. It also contains:

- sodium chloride
- sodium hydroxide
- sterile water

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

Sponsor

Australian Sponsor:

Pfizer Australia Pty Ltd
Sydney, NSW
Toll Free number: 1800 675 229.
www.pfizer.com.au

This leaflet was revised in March 2020.

7.5 mg/0.3mL AUST R 279543

10 mg/0.4mL AUST R 279544

15 mg/0.6mL AUST R 279551

20 mg/0.8mL AUST R 279552

25 mg/1.0 mL AUST R 279553