

METHOTREXATE INJECTION BP

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Methotrexate Injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Methotrexate Injection against the benefits this medicine is expected to have for you.

This medicine is likely to be used while you are at the clinic or in hospital. If possible, please read this leaflet carefully before this medicine is given to you. In some cases this leaflet may be given to you after the medicine has been used.

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

Keep this leaflet.

You may need to read it again.

What Methotrexate Injection is used for

Methotrexate belongs to a group of anticancer drugs known as antineoplastics. Methotrexate works by preventing the growth of certain cells. It is used for different types of cancer and also severe psoriasis (a skin condition).

Methotrexate Injection may be used for the treatment of other conditions that are not mentioned above. Your doctor will be able to tell you about the specific condition for which you have been prescribed it.

This medicine is available only with a doctor's prescription.

Before you are given Methotrexate Injection

When you must not be given it

Do not use Methotrexate Injection if:

- you have an allergy to methotrexate or any of the ingredients listed at the end of this leaflet
- you have kidney disease or poor kidney function
- you have liver disease or poor liver function
- you are pregnant or planning to get pregnant
- you are breastfeeding
- you have a problem with your immune system such as severe or repeated infections
- you have a problem with your blood such as anaemia
- you are receiving radiotherapy e.g. X-rays, ultra violet radiotherapy
- you have a stomach ulcer or ulcerative colitis (bleeding from your bowel)
- you are an alcoholic
- you have an infection

If you are not sure whether any of these apply to you, check with your doctor.

Before you are given it

Both you and your partner must use a reliable method of contraception (birth control) during treatment with Methotrexate Injection.

Tell your doctor if:

1. you have any allergies to:

- any other medicine
- any other substances, such as foods, preservatives or dyes

2. if you are pregnant or intend to become pregnant.

Methotrexate Injection may affect your developing baby if you take use it during pregnancy. If it is necessary for you to be given it, your doctor or pharmacist will discuss the risks and benefits of taking/using it during pregnancy.

3. you are breastfeeding or plan to breastfeed

Methotrexate Injection passes into breast milk and should not be used when breastfeeding.

4. you have or have had any medical conditions, especially the following:

- any sort of infection or immune system disorder e.g. sinusitis, tooth abscess etc
- stomach ulcer or ulcerative colitis (bleeding from your bowel)
- fluid or swelling in your abdomen or stomach
- fever, chills, sore throat or mouth ulcers
- bleeding or bruising more than usual
- tiredness, headaches, shortness of breath, dizziness, looking pale

If you have not told your doctor or pharmacist about any of the above, tell them before you are given Methotrexate Injection.

Taking other medicines

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

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

- other anticancer drugs such as cisplatin, mercaptopurine or asparaginase
- antibiotics or antimalarial drugs
- aspirin and other pain killers
- medicines to relieve swelling or inflammation including medicines for arthritis
- medicines for epilepsy such as phenytoin
- corticosteroids such as hydrocortisone and prednisolone
- medicines for diabetes such as sulphonylureas
- medicines that reduce cholesterol such as cholestyramine
- medicines for gout such as probenecid
- vitamin preparations that contain folic acid
- medicines for psoriasis such as etretinate
- medicines for heart problems such as amiodarone
- medicines used to treat asthma and related compounds such as theophylline

Methotrexate Injection can also be affected by the following:

- blood transfusions
- nitrous oxide anaesthetics
- vaccinations
- alcohol
- radiation e.g. X-rays, radiotherapy

Your doctor will advise you about continuing to take other medicines while you are receiving methotrexate.

You may need different amounts of your medicine, or you may need to take/use different medicines. Your doctor or pharmacist will advise you.

How Methotrexate Injection is given

Methotrexate is given by injection into a vein, muscle or directly into the fluid around your spinal cord. Methotrexate must only be given by a doctor or nurse.

Your doctor will decide what dose, how often and how long you will receive it. This depends on your condition and other factors, such as your weight, age, blood tests, how well your kidneys and liver are working, and whether or not other medicines are being given at the same time.

If you are given too much (overdose)

This rarely happens as Methotrexate Injection is administered under the care of a highly trained doctor. However, if you are given too much methotrexate, you may experience some of the effects listed under "Side effects" below.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

If you experience severe side effects, tell your doctor immediately, or go to the nearest hospital emergency department.

While you are being treated with Methotrexate Injection

- **Both you and your partner must use a reliable method of contraception (birth control) during and for at least 3 months after treatment with Methotrexate Injection.**

This is because methotrexate can cause damage to the baby during pregnancy and can also cause genetic problems if the baby is conceived while you are taking methotrexate.

- **Try to stay out of the sun and do not use sunlamps.** Methotrexate can increase your sensitivity to sunlight and cause severe reactions.
- **Do not drink any alcohol while you are being treated with Methotrexate Injection, as this may cause permanent liver damage.**
- **Do not drive or operate machinery until you know how methotrexate affects you.** Methotrexate may cause dizziness or tiredness in some people and therefore may affect alertness.
- **If you can, avoid people with infections.** Check with your doctor immediately if you think that you are getting an infection or if you get a fever or chills, cough or hoarseness, lower back or side pain, or painful or difficult urination.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Methotrexate Injection.

Like other medicines, methotrexate can cause some side effects. If they occur, most are likely to be minor or temporary. However, some may be serious and need medical attention.

Ask your doctor or nurse to answer any questions that you may have.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

- severe abdominal pain, or diarrhoea
- nausea or vomiting, especially vomiting blood
- an increased tendency to bleed, unusual bruising or get infections
- swelling of the face, lips or tongue
- rash, redness, hives, itching, pinpoint red spots or painful blistering resulting in peeling of layers of the skin
- lighter patches on the skin, yellowing of the skin/eyes (jaundice)
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson syndrome)

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

All of these side effects are very rare.

Tell your doctor or nurse immediately if you notice any of the following:

- infection of hair roots or hair loss, especially of the scalp
- frequent or painful urination (cystitis/dysuria), or blood in the urine
- changes in the menstrual cycle (periods)
- bleeding gums, sore mouth, difficulty swallowing, cold sores, mouth ulcers
- coughing, wheezing, difficulty breathing, chest pain
- black tarry stools or blood in the stools
- fits

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

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

- blurred vision
- ringing in the ears
- conjunctivitis (itchy eyes and crusty eyelids)
- fever and chills, sore throat, sweats or feel generally unwell
- tiredness, headaches, shortness of breath, dizziness, looking pale
- sensitivity to the sun
- acne or boils or skin ulcers
- lack of appetite or weight loss
- difficulty speaking, writing etc
- drowsiness
- weakness, numbness or paralysis
- feeling thirsty
- irritability, depression, confusion or mood changes
- changes in the toenails or fingernails

These are the more common side effects of methotrexate.

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor. Other side effects may be only seen by blood tests. Your doctor will carry out any necessary tests.

Storage

Methotrexate Injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Product Description

What it looks like

Methotrexate Injection is a yellow to orange solution in a plastic vial.

Methotrexate Injection can be identified by an Australian Registration Number, which is found on the packaging:

- Aust R 10777: Methotrexate Injection 50mg in 2mL
- Aust R 47648: Methotrexate Injection 500mg in 20mL
- Aust R 10778: Methotrexate Injection 1000mg in 10mL

Ingredients

Methotrexate Injection BP contains Methotrexate BP and Sodium Hydroxide BP in Water for Injections BP. The 2ml and 20ml presentations contain Sodium Chloride BP. It does not contain a preservative.

Manufacturer

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Sponsor and Distributor in Australia

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