

Consumer Medicine Information**What is in this leaflet**

This leaflet answers some common questions about Methotrexate Ebewe. 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 Ebewe 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. For any further information please see your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Methotrexate Ebewe is used for

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

Methotrexate Ebewe 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 Methotrexate Ebewe.

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

Methotrexate is not recommended for use in children, as there is not enough information on its effects in children.

Before you are given Methotrexate Ebewe**When you must not be given it**

Do not use Methotrexate Ebewe if:

- you have an allergy to Methotrexate Ebewe 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)
- bone marrow disease
- you are an alcoholic
- you have an infection

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

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 Methotrexate Ebewe.

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 are given it

The medicine may cause birth defects if either you or your partner is taking it. Both you and your partner must use a reliable method of contraception (birth control or condom) using treatment with Methotrexate Ebewe and for at least 6 months 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.

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 Ebewe 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 Ebewe 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
- diabetes
- cancer
- folate deficiency

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

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

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.

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

- other anticancer drugs such as cisplatin, cytarabine, mercaptopurine or asparaginase
- antibiotics or antimalarial drugs including tetracyclines, penicillins, sulphonamides, trimethoprim and chloramphenicol, pyrimethamine
- aspirin and other pain killers
- medicines to relieve swelling or inflammation including medicines for arthritis
- non-steroidal anti-inflammatory drugs, used to help with pain relief, such as azapropazone, diclofenac, indomethacin and ketoprofen
- triamterene, a medicine to remove fluid or water from the body
- 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 and allopurinol
- 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
- azathioprine, a medicine used to prevent transplant organ rejection
- retinoids (acitretin or etretinate) medicines used to treat skin conditions
- proton pump inhibitors, such as omeprazole, esomeprazole or pantoprazole

Methotrexate Ebewe 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 medicines, or you may need to take/use different medicines. Your doctor or pharmacist will advise you.

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

How Methotrexate Ebewe is given**How much is given**

Your doctor will decide what dose of Methotrexate Ebewe you will receive. This depends on your condition and other factors,

such as your weight, and other medicines you are being given. This medicine may be given alone or in combination with other drugs. It may be given as a short course or on an ongoing basis. Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any unwanted effects have been controlled. For cancer treatment, several courses of Methotrexate Ebewe therapy may be needed depending on your response to treatment. For the treatment of psoriasis, Methotrexate Ebewe therapy is usually required on an ongoing basis.

Ask your doctor if you want to know more about the dose of Methotrexate Ebewe you receive.

How it is given

Methotrexate Ebewe may be given as an injection into a vein. Methotrexate Ebewe must only be given by a doctor or nurse.

If you are given too much (overdose)

This rarely happens as Methotrexate Ebewe 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.

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.

Your doctor has information on how to recognise and treat an overdose.

Ask your doctor if you have any concerns.

While you are being treated with Methotrexate Ebewe

Things you must do

- **Tell your other doctors, dentists, and pharmacists if you are taking any other medicines.**
- **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 contraception (birth control) during and for at least 6 months after treatment with Methotrexate Ebewe. 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.**

- 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.

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

It may affect other medicines used during surgery.

- **Try to stay out of the sun and do not use sunlamps.** Methotrexate Ebewe can increase your sensitivity to sunlight and cause severe reactions and increase risk of skin cancer (non-melanoma and melanoma). Some signs are:
 - redness
 - itching
 - swelling
 - blistering
 - rashIf you need to be in the sun, use a 30+ sunscreen and wear a hat and shirt to protect your skin from the sun.
- **Do not drink any alcohol while you are being treated with Methotrexate Ebewe, as this may cause permanent liver damage.**
- **Do not drive or operate machinery until you know how Methotrexate Ebewe affects you.** Methotrexate Ebewe 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 you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.
- Be careful when using a toothbrush, toothpick or dental floss.
- Be careful not to cut yourself
- 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.
- 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.
- 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.

Side effects

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

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, upset stomach, or diarrhoea
- nausea or vomiting, especially vomiting blood, loss of appetite
- mild dizziness
- mild chills
- mild headache
- sore eyes
- an increased tendency to bleed, unusual bruising or get infections
- swelling of the face, lips or tongue or other parts of the body e.g. hands ankles or feet
- 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)
- high fever, chills, headache, confusion and rapid breathing (serious blood infection)

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, or bowel motions
- changes in the menstrual cycle (periods)
- bleeding gums, sore mouth, difficulty swallowing, cold sores, mouth ulcers, swollen glands (lymph nodes)
- coughing, wheezing, difficulty breathing, chest pain
- black tarry stools or blood in the stools
- fits, seizures or convulsions

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, short term blindness
- 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, muscle cramps, spasms

- feeling thirsty
- irritability, depression, confusion or mood changes
- changes in the toenails or fingernails or skin around the nails
- impotence or loss of interest in sex
- painful muscles and joints
- back pain
- stiff neck

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 urine or other tests. Your doctor will carry out any necessary tests. Some side effects of methotrexate may occur after you stop taking it.

Storage

Methotrexate Ebewe will be stored in the pharmacy, doctor's surgery or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C. Do not freeze.

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.

Product Description

What it looks like

Methotrexate Ebewe is a clear yellow liquid in glass vials.

Ingredients

Methotrexate Ebewe contains Methotrexate as the active ingredient. It also contains:

- water for injections
- sodium hydroxide

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

Methotrexate Ebewe comes in the following strengths and pack sizes:

500 mg in 5 mL vial - AUST R 98546

1000 mg in 10 mL vial - AUST R 98547

5000 mg in 50 mL vial - AUST R 120618

Manufacturer

EBEWE Pharma Ges.m.b.H. Nfg. KG
A-4866 Unterach
Austria

Sponsor

Methotrexate Ebewe is distributed in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park
Australia
Tel: 1800 634 500

Methotrexate Ebewe is distributed in New Zealand by:

Novartis New Zealand Ltd
PO Box 99102
Newmarket
Auckland 1149
Tel: 0800 354 335

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