

METHOTREXATE EBewe®

methotrexate

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)
- 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 Ebewe.

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 therefore there is a possibility that the breast-fed baby may be affected.

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 Ebewe.

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.

Some medicines and Methotrexate Ebewe 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
- theophylline, a medicine used to relieve asthma
- fluid tablets
- 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 which can affect the liver such as azathioprine, leflunomide, retinoids or sulfasalazine

- pyrimethamine, a medicine used for malaria)
- methoxsalen (a medicine used with ultraviolet light in PUVA therapy for conditions such as severe psoriasis).
- medicines used to treat asthma and related compounds such as theophylline.

These medicines may be affected by Methotrexate Ebewe or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you about continuing to take other medicines while you are receiving Methotrexate Ebewe.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Methotrexate Ebewe can also be affected by the following:

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

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)

As Methotrexate Ebewe will most likely be given to you in hospital or under the supervision of your doctor, it is very unlikely that you will receive an overdose.

However, if you experience severe side effects tell your doctor immediately or go to Accident and Emergency at the nearest hospital. You may need urgent medical attention.

Symptoms of a Methotrexate Ebewe overdose may include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature. They may include blood in your bowel motions or black, tarry bowel motions, bleeding, nausea, vomiting, mouth ulcers and severe infections.

While you are using Methotrexate Ebewe

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Methotrexate Ebewe.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given this medicine.

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.

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

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and to check for any unwanted side effects.

Be careful to use an effective method of contraception while you are being treated with Methotrexate Ebewe and for at least 12 weeks after stopping treatment.

Your doctor will tell you what forms of contraception are suitable and when it is safe to stop using contraception if you wish to do so.

If you or your partner becomes pregnant while you are being treated with Methotrexate Ebewe, or for up to 12 weeks afterwards, tell your doctor immediately.

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.

Protect your skin when you are in the sun, especially between 10am and 3pm. If outdoors, wear protective clothing and use a 15+ sunscreen. Avoid exposure to sunlamps.

Methotrexate Ebewe may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or a severe sunburn.

Methotrexate Ebewe can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk of infection or bleeding:

- **Avoid people who have 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. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.**
- **Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.**
- **Avoid contact sports or other situations where you may bruise or get injured.**

Methotrexate Ebewe may be excreted in body fluids and waste, including blood, urine, faeces, vomitus and semen. In general, precautions to protect other people should be taken while you are receiving Methotrexate Ebewe and for one week after the treatment period by:

- Flushing the toilet twice to dispose of any body fluids and waste.
- Wearing gloves to clean any spill of body fluid or waste. Use paper towels or old rags, a strong solution of non-bleaching detergent and large amounts of water to mop up the spill. Discard the towels or rags into a separate waste bag and dispose of fluids in the toilet.
- Wash linen or clothing that is heavily contaminated by body fluids or waste separately from other items. Use a strong solution of non-bleaching detergent and large amounts of water.
- Place soiled disposable nappies and other pads in a plastic bag,

seal and dispose into the garbage.

- For sexual intercourse, use a barrier method such as a condom.

Things you must not do

You must not drink alcohol whilst you are being given this medicine.

Alcohol may increase the side effects of Methotrexate Ebewe and may cause permanent liver damage.

Things to be careful of

Be careful driving or machinery until you know how Methotrexate Ebewe affects you.

This medicine may cause dizziness, drowsiness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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

This medicine may have unwanted side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

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

You may not experience any of them.

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

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

- mild nausea or vomiting
- stomach pains

- tiredness
- mild chills and fever
- dizziness
- drowsiness
- increased burning of the skin from sun exposure
- acne or boils or skin ulcers
- infection of hair roots or hair loss (usually occurs only with high doses of Methotrexate Ebewe)
- inflamed mouth gums
- inflamed mucous membranes (mucositis) or sore mouth
- loss of appetite or weight loss
- changes in menstrual cycle
- unusual vaginal discharge
- headaches
- feeling thirsty
- changes in toenails or fingernails
- eye discomfort or conjunctivitis (itchy eyes and crusty eyelids)
- ringing in the ears.

The above list includes the more common side effects of your medicine. They are usually mild.

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

- diarrhoea
- vomiting
- mouth ulcers
- skin rash, itchiness
- dry, non-productive cough
- signs of an infection (such as fever, chills, sore throat, cough)
- difficulty speaking, writing etc
- back pain
- stiff neck
- irritability, depression, confusion or mood changes
- altered conscious state
- painful urination or difficulty urinating, lower back or side pain (these may be symptoms of kidney disease)
- muscle cramps, spasms, weakness or paralysis
- painful joints

- blurred vision or impaired vision.

These may be serious side effects. The above list includes serious side effects which may require medical attention.

If any of the following happen, tell your doctor or nurse 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, rash, itching or hives on the skin.
- unusual bleeding or bruising (including blood in your stools or urine).
- yellowing of the skin and eyes, nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, and dark coloured urine (these may be symptoms of a type of liver disease called hepatitis)
- chest pain
- seizures (fits)
- skin ulceration or severe skin rash in the lips, eyes, mouth, nose and genitals (Steven-Johnson syndrome).

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

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

The benefits and side effects of Methotrexate Ebewe may take some time to occur. Therefore even after you have finished your Methotrexate Ebewe treatment you should tell your doctor immediately

if you notice any of the side effects listed in this section.

After being given Methotrexate Ebewe

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 Ebewe 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:

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Methotrexate Ebewe is distributed
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This leaflet was updated on June
2019.