

Packageleaflet: information for the patient
**Etoposid “Ebewe” 20 mg/ml
concentrate for solution for infusion**
Etoposide

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any side effects not listed in this leaflet.

What is in this leaflet

1. What Etoposid “Ebewe” is and what it is used for
2. What you need to know before you are given Etoposid “Ebewe”
3. How you are given Etoposid “Ebewe”
4. Possible side effects
5. How to store Etoposid “Ebewe”
6. Contents of the pack and other information

1. What Etoposid “Ebewe” is and what it is used for

Etoposid “Ebewe” is an anti-cancer medicine, in the form of a concentrate for solution for infusion (a concentrated solution which is diluted to make a solution which can be given as a slow injection via a drip). Etoposid “Ebewe” is used in the treatment of small cell lung cancer, testicular cancer and cancer of the blood-forming tissues of bone marrow (acute myelomonocytic and myelocytic leukaemia). It is often used at the same time as other anti-cancer medicines.

Etoposid “Ebewe” works by interfering with the production of new DNA, which is needed to make more cells. Therefore, when Etoposid “Ebewe” is taken up by the cancer cells, it stops the growth of new cancer cells.

2. What you need to know before you are given Etoposid “Ebewe”

Do not use Etoposid “Ebewe”:

- if you are allergic to etoposide or any of the other ingredients of this medicine (listed in section 6).
- If your liver is not working properly
- If your kidneys are not working properly
- If your bone marrow is not producing enough blood cells
- If you are breast-feeding
- If you have a weak immune system and you are being vaccinated against yellow fever at the same time as

Etoposid “Ebewe” must not be injected into an artery or into a body cavity (e.g. your belly).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are using Etoposid “Ebewe”

- If you have received radiation therapy or therapy with other cancer agents. Treatment should not be started until your bone marrow has regenerated and is producing enough blood cells
- If you have an infection, this must be healed before treatment is started
- You might experience allergic reactions such as feeling hot, fast heartbeat and problems with breathing
- You might feel sick and vomit. Your treating physician might prescribe your medication to prevent this.
- Your treating physician might decide to change the treatment if
 - you have received radiotherapy or therapy with other cancer agents previously
 - if your heart is beating irregularly or have suffered a heart attack
 - if your liver and kidneys are not working properly
 - if you have tingling or itching in your hands and feet
 - if you have problems with passing urine
 - if you suffer from epilepsy
 - if you have an inflammation or sores in your mouth
- You might develop an special type of leukaemia after treatment with Etoposid “Ebewe”.
- Both, male and female patients should use an effective contraception during treatment and for up to 6 months after treatment. If you are a man, there is a possibility of irreversible infertility; please talk to your doctor about the possibilities of sperm conservation.
- Effective anti-cancer treatment can destroy cancer cells rapidly in large numbers. On very rare occasions this may cause harmful amounts of substances from these cancer cells to be released into the blood. If this happens it can cause problems with the liver, kidney, heart or blood, which may result in death if not treated. In order to prevent this, your doctor will need to do regular blood tests to monitor your liver and kidney function as well as blood cell counts during treatment with this medicine.
- If your skin comes in contact with Etoposid “Ebewe”, wash thoroughly with water.

Etoposid “Ebewe” should only be administered by health professionals experienced in the use of antineoplastic treatment.

Other medicines and Etoposid “Ebewe”

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

If you receive radiotherapy or medicines which damage the bone marrow, the toxic effect of cause Etoposid “Ebewe” on the bone marrow might get worse.

If you are taking ciclosporin (e.g. used in transplant patients), the toxic effects of Etoposid “Ebewe” might get worse because it is excreted from the body more slowly.

If you are taking medicines for thinning the blood (anticoagulants), please talk to your doctor as the dose might have to be adjusted.

Medicines containing phenylbutazone, sodium salicylate or salicylic acid (mostly used as pain killers) may interfere with the metabolism of Etoposid “Ebewe”.

You should not receive vaccination with live vaccines (e.g. for yellow fever) during therapy with Etoposid “Ebewe”.

Tell your doctor if you are taking a medicine containing disulfiram (used for treating alcohol dependency) as Etoposid “Ebewe” contains alcohol.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Etoposid “Ebewe” may harm your baby when given during pregnancy. It should therefore not be used unless your physician decides that the benefit for you is bigger than the risk for your baby. Your doctor will discuss this with you in detail if necessary.

You have to stop breast-feeding if you are being treated with Etoposid “Ebewe”.

Driving and using machines

Do not drive or use any tools or machines shortly after treatment with Etoposid “Ebewe” as it may make you feel very sleepy or you might not be able to see for a short time.

Etoposid “Ebewe” contains alcohol.

3. How Etoposid “Ebewe” will be given to you

This medicine will be administered by medical personnel; do not take it yourself.

The dose will be individually calculated for you and depends on your type of cancer, if Etoposid “Ebewe” is given alone or in combination and on your general condition.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are very rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately

Very common (may affect more than 1 in 10 people)

- Bone marrow is not producing enough blood cells (myelosuppression); especially white blood cells (leucopenia) and platelets (thrombocytopenia). This usually resolves 3 weeks after the last dose.
- Low counts of red blood cells (anaemia)
- lower white blood cell count (sometimes severe with increased risk of severe infection) (neutropenia)
- Feeling sick and vomiting
- Diarrhoea and loss of appetite (anorexia)
- Abdominal pain
- constipation
- Hair loss resulting in total baldness (alopecia, grows back after end of therapy)
- Liver damage
- Pigmentation
- Feeling of weakness,
- Generally feeling unwell

Common (may affect up to 1 in 10 people)

- Acute leukaemia
- Inflammation of the stomach and the gullet (oesophagus) (stomatitis and esophagitis)
- Diarrhoea
- Serious attacks and rhythm disturbances (myocardial infarction, arrhythmia)
- Serious allergic reaction which causes difficulty in breathing or dizziness
- Dizziness
- Low blood pressure (hypotension) may occur if the infusion is administered too rapidly
- Rash, change of skin colour and itching (urticarial, pruritus)
- Inflammation of veins (phlebitis)
- Leakage of the infusion solution into the surrounding tissue with swelling, pain and skin toxicity
- Tingling and prickling in hands and feet (peripheral neuropathy)

Uncommon (may affect up to 1 in 100 people)

- Convulsion
- Inflammation of the lungs (Interstitial pneumonitis) and lung damage (pulmonary fibrosis), cough, laryngospasm (throat spasm), cyanosis (lack of oxygen), breathing arrest (apnoea)
- Inflammation of the eye nerves (Opticus neuritis)
- Increase in liver enzymes,
- Swelling of the face and tongue,
- Sweating

11782025-04

Rare (may affect up to 1 in 1,000 people)

- Cramps (seizure)
- Fever
- Confusion, feeling sleepy, aftertaste and loss of sight for a short time
- Difficulty in swallowing, disturbed sense of taste

Very rare (may affect up to 1 in 10,000 people)

- Severe skin reactions due to an allergic reaction (Stevens-Johnson syndrome; toxic epidermal necrolysis), symptoms include fever, general ill feeling, itching of the skin, joint aches, multiple skin lesions or blisters, which may involve the face or lips.
- inflammation of skin (Radiation recall dermatitis)

Not known: frequency cannot be estimated from the available data

- Kidneys: Etoposide has been shown to reach high concentrations in the kidneys and can possibly inhibit their function.
- Reproductive system: Amenorrhoea, anovulatory cycles, decreased fertility and hypomenorrhoea.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Etoposid “Ebewe”

Etoposid “Ebewe” will be stored in the pharmacy and made up in a special area before the doctor or nurse gives it to you. It should be stored in room temperature and should be kept in the original package.

Keep out of the reach and sight of children.

Do not use Etoposid “Ebewe” after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Content of the pack and other information

What Etoposid “Ebewe” contains

- The active substance is etoposide.
- The other ingredients are 20 mg/ml benzyl alcohol, ethanol 96% (v/v), anhydrous citric acid, macrogol 300, polysorbate 80.

What Etoposid “Ebewe” looks like and contents of the pack

Etoposid “Ebewe” is a clear, light yellow colour solution.

Pack sizes: Vials with 50 mg/2.5 ml, 100 mg/5 ml, 200 mg/10 ml, 400 mg/20 ml, 1.0 g/50 ml.

Marketing Authorisation Holder:

EBEWE Pharma Gesm.b.H. Nfg. KG

A-4866 Unterach, Austria

Manufacturer:

EBEWE Pharma Ges m.b.H. Nfg. KG

A-4866 Unterach, Austria

This leaflet was last approved in April 2013

The following information is intended for healthcare professionals only:

Instructions for use and handling and disposal:

Handle according to guidelines for cytotoxics.

Concentrate for solution for infusion must not be used undiluted.

Should only be diluted with isotonic sodium chloride or isotonic glucose infusion solutions. The concentration of Etoposid “Ebewe” in the reconstituted solution for infusion should not exceed 0.4 mg/ml due to the risk of precipitation.

As with other potentially cytotoxic compounds caution should be exercised when handling Etoposid “Ebewe” (gloves, mask, overall). Contact with skin and mucous membranes should be avoided.

If Etoposid “Ebewe” comes into contact with skin wash with water.

Only for intravenous use.

Single use only.

Unused solution should be discarded.

Syringes, containers, absorbent materials, solution and any other contaminated material should be placed in a designated impervious container and incinerated, in accordance with local procedures.

Only clear solutions practically free from particles should be used.

Cytotoxics should not be handled by pregnant personnel.

Incompatibilities

Etoposid “Ebewe” should not be physically mixed with any other medicine. It should only be diluted with isotonic sodium chloride or isotonic glucose infusion solutions.

Plastic devices made of acrylic or ABS polymers have been reported to crack when used with undiluted Etoposid “Ebewe”, concentrate for solution for infusion 20 mg/ml. This effect has not been reported with Etoposid “Ebewe” after dilution of the concentrate for solution for infusion according to instructions.

Special precautions for storage

No special precautions for storage for the concentrate.

Chemical and physical in-use stability has been demonstrated for 24 hours at room temperature. From a microbiological point of view, the diluted medicinal product should be used immediately. If not used immediately, in-use storage times and conditions prior to the use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.