

Etoposide Ebewe®

Etoposide Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Etoposide Ebewe. It does not contain all the available information.

It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Etoposide Ebewe against the benefits they expect it will have for you.

This medicine is likely to be used while you are 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 being given this medicine, ask your doctor or pharmacist.

Keep this leaflet in a safe place. You may need to read it again.

What is Etoposide Ebewe used for

Etoposide belongs to a group of medicines known as antineoplastic or cytotoxic agents. You may also hear it referred to as a chemotherapy medicine.

It is used to treat lung cancer, leukaemia (blood cancer) and cancer of the lymph glands. It interferes with the development of cells and causes cell death, particularly in cancer cells.

Etoposide Ebewe may be used alone or in combination with other medicines to treat cancer.

Your doctor may have prescribed Etoposide Ebewe for another reason. Ask your doctor if you have any questions about why Etoposide Ebewe has been prescribed for you.

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

Before you are given Etoposide Ebewe

When you must not be given it

Etoposide Ebewe should not be given to you if you have an allergy to etoposide or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to etoposide may include:

- chills/fever
- fast heart beat
- 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
- dizziness or light headedness
- flushing, sweating

Etoposide Ebewe should not be given to you if you have, or have had any of the following medical conditions, unless you have discussed it with your doctor:

- you have bone marrow suppression (decreased blood cell production)

- you have severe liver or renal disease
- a blood disorder with a reduced number of white blood cells
- a blood disorder in which there is a decreased number of red blood cells
- a blood disorder with a low blood platelet count

Etoposide Ebewe should not be given with concomitant use of yellow fever vaccine or other live vaccines in immunocompromised patients.

Etoposide Ebewe should not be given to you if you have had recent surgery.

Etoposide Ebewe should not be given to you if you are receiving radiation therapy or any other medicines which lower your immune system.

Etoposide Ebewe should not be given to you if you are pregnant or intend to become pregnant and if you are breast feeding.

Like most medicines used to treat cancer, Etoposide Ebewe is not recommended for use during pregnancy and lactation, unless you and your doctor have discussed the risks and benefits involved.

You and your partner must use a reliable method of contraception (birth control) during treatment with Etoposide Ebewe and for at least 12 weeks after you stop using it.

This medicine may cause birth defects if either the male or female is receiving it at the time of conception or if it is used during pregnancy.

In addition, many cancer medicines can cause infertility. Your doctor should discuss this issue with you

before you begin therapy with etoposide.

Do not breastfeed while you are on treatment with Etoposide Ebewe, unless you have discussed it with your doctor.

Etoposide Ebewe passes into human breast milk. As Etoposide Ebewe may cause serious side effects in a breast fed baby, breast feeding is not recommended while you are receiving it.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- etoposide
- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- kidney or liver disease
- infection or high temperature

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold is not usually a reason to delay treatment.

Taking other medicines

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

Some medicines and etoposide may interfere with each other. This includes:

- levamisol (ergamisol) – a
- medicine that is used to treat some other forms of cancer

- cyclosporin - a medicine used to prevent rejection of transplanted organs
- cisplatin
- anti-epileptics
- warfarin
- any medicines which suppress your immune system.

These medicines may be affected by Etoposide Ebewe, or affect how well it works. You may need different amounts of your medicine, or you may need to have different medicines. Your doctor will advise you.

While you are being treated with etoposide, and for about one month after you stop treatment with it, do not have any immunisations (vaccinations) without your doctor's approval. Etoposide may lower your body's resistance and there is a chance you may get the infection the immunisation is meant to prevent. In addition, other persons living in your household should not take oral polio vaccine (sabin) since there is a chance they could pass the polio virus on to you.

If you have not told your doctor about any of the above, tell them before you start Etoposide Ebewe. If you are not sure whether you should be given Etoposide Ebewe, talk to your doctor.

How Etoposide Ebewe is given

How much is given

Your doctor will decide what dose of etoposide you will receive.

Your dose of Etoposide Ebewe is worked out based on your body weight and height and on the type of cancer you have. The dose worked out for you may be different to the dose of another patient.

Etoposide Ebewe may be given alone or in combination with other anti-cancer drugs.

Several courses of Etoposide Ebewe therapy may be needed depending on your response to treatment.

Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any uncontrolled effects have been controlled.

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

How it is given

Etoposide Ebewe should only be prepared, administered and monitored by a doctor or nurse.

Etoposide Ebewe is given as an intravenous infusion (ie. a slow injection via a "drip" into a vein).

How long is it given

Etoposide Ebewe is usually given each day for 5 days. This is followed by a treatment-free interval of 2-4 weeks. This is called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need.

If you are given too much (overdose)

As your dose of Etoposide Ebewe will be determined and administered by a medical specialist the chance of receiving an overdose is most unlikely. However, if an overdose is given, your specialist will give you the appropriate treatment.

If you experience severe side effects tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital.

Symptoms of an etoposide overdose include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

While you are being given Etoposide Ebewe

Tell your doctor, nurse or pharmacist if you have any concerns before, during or after administration of Etoposide Ebewe.

Etoposide Ebewe is known to be powerful at reducing the body's ability to make blood cells.

Therefore, regular blood tests will be required.

Etoposide should not be used during pregnancy unless the clinical condition of the woman requires treatment with etoposide.

Things you must do

Be sure to keep all 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 detect any unwanted side effects.

Keep follow up appointments with your doctor.

It is important to have your follow-up infusions of Etoposide Ebewe at the appropriate time to get the best effect from your treatments.

If you forget an appointment, contact your doctor immediately.

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

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are undergoing therapy with Etoposide Ebewe.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are undergoing therapy with Etoposide Ebewe.

If you become pregnant or are breastfeeding while undergoing therapy with Etoposide Ebewe, tell your doctor.

Etoposide 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 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 regular toothbrush, dental floss or toothpick. Your doctor, dentist, pharmacist or nurse may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work done;
- 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.

Things you must not do

Do not drink alcohol while taking Etoposide Ebewe.

You may feel flushed or get headaches.

Things to be careful of

Be careful when driving or operating machinery until you know how Etoposide Ebewe affects you.

As with other medicines used to treat cancer, Etoposide Ebewe may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to Etoposide Ebewe before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given Etoposide Ebewe, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines that treat cancer, etoposide may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of the side effects.

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

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

These are the more common side effects of Etoposide Ebewe

- nausea, vomiting, diarrhoea or constipation
- loss of appetite
- soreness or ulceration of the mouth
- stomach pain, constipation, altered taste
- unusual hair loss or thinning
- dizziness, light-headedness
- feeling tired or weak
- problems swallowing
- low/high blood pressure
- pigmentation, rash, pruritus, urticaria

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

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

- frequent infections such as fever, severe chills, sore throat and mouth ulcers
- bleeding or bruising more easily than normal, nose bleeds, rash of small reddish-purple spots on your skin, blood in your stool or urine
- tiredness, headaches, being short of breath when exercising,

- dizziness and looking pale, fast heart rate
- numbness, tingling and pain in hands or feet
 - itching of the skin, joint aches, blisters that look like hives on the upper body, legs, arms, palms, hands, or feet and may involve the face or lips,
 - yellowing of the skin or whites of the eyes
 - abdominal pain
 - abnormal physical weakness or lack of energy
 - sore mouth, eye pain, vision problems
 - burning, stinging, pain, redness or swelling at the injection site

Tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital if you notice any of the following signs of a sudden life-threatening allergic reaction:

- fast heartbeat, chills and fever; shortness of breath, wheezing, coughing or difficulty breathing; dizziness, flushing, sweating, swelling of the face, lips, tongue or other parts of the body, itching or hives on the skin

Treatment with etoposide may cause changes in your blood cells which may be serious. Etoposide may also affect how your kidneys and liver work. Your doctor will arrange regular blood tests and checks to detect any changes.

Some people may get other side effects while being given etoposide.

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

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

After being given Etoposide Ebewe

The benefits and side effects of Etoposide Ebewe may take some

time to occur. Therefore even after you have finished your Etoposide Ebewe treatment you should tell your doctor immediately if you notice any of the side effects listed in the previous section.

Storage

Etoposide Ebewe will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place where the temperature stays below 25°C. Protect from light.

After use, any unused portion of the vial will be discarded.

Product description

What it looks like

Etoposide Ebewe is a clear, colourless to yellow liquid contained in a clear glass vial.

Etoposide Ebewe is available in:

- 50mg of etoposide per 2.5mL vial, 1's
- 100mg of etoposide per 5mL vial, 1's and 5's
- 200mg of etoposide per 10mL vial, 1's
- 400mg of etoposide per 20mL vial, 1's
- 1000mg of etoposide per 50mL vial, 1's

Not all strengths may be marketed in Australia.

Ingredients

Active ingredient:

- etoposide

Other ingredients:

- citric acid
- macrogol 300
- ethanol
- polysorbate 80
- benzyl alcohol

Etoposide Ebewe does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Manufacturer

Ebewe Pharmaceuticals Ltd
A-4866
Unterach
Austria, Europe

Distributor

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

Australian Registration Numbers

50mg injection: AUST R 96636 (vial)

100mg injection: AUST R 96641 (vial)

200mg injection: AUST R 96642 (vial)

400mg injection: AUST R 96643 (vial)

1000mg injection: AUST R 96644 (vial)

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