

ETOPOPHOS®

etoposide phosphate(e-TOE-poe-side fos-FATE)

Consumer Medicine Information

What is in this leaflet

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ETOPOPHOS against the benefits they expect it will have for you.

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 ETOPOPHOS is used for

ETOPOPHOS is used to treat lung cancer, leukaemia (blood cancer), cancer of the lymph glands and testicular cancer.

ETOPOPHOS contains etoposide phosphate, an anti-cancer medicine. It interferes with the development of cells and causes cell death, particularly in cancer cells.

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

Your doctor may have prescribed ETOPOPHOS for another reason. Ask your doctor if you have any questions about why ETOPOPHOS was prescribed for you.

Before you are given ETOPOPHOS

When you must not be given it

Do not have ETOPOPHOS if you have an allergy to ETOPOPHOS, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- chills/fever
- fast heart beat
- difficulty in breathing, shortness of breath
- dizziness or light headedness
- flushing, sweating
- swelling of the face, tongue or other parts of the body

Do not take ETOPOPHOS if you have, or have had any of the following medical conditions, unless you have discussed it with your doctor:

- liver problems
- kidney 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

Tell your doctor if you have allergies to:

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

Tell your doctor if you have an infection or high temperature.

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.

Do not take ETOPOPHOS if you have had recent surgery.

Do not take ETOPOPHOS if you are receiving radiation therapy or any other medicines which lower your immune system.

Do not take ETOPOPHOS if you are pregnant or intend to become pregnant.

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

You should use some kind of birth control while you are having ETOPOPHOS and for at least 12 weeks after you stop using it.

ETOPOPHOS may cause birth defects if either the male or female is using it at the time of conception.

Do not breastfeed while having ETOPOPHOS, unless you have discussed it with your doctor.

It is not known whether ETOPOPHOS passes into breast milk. Therefore there is a possibility that the breast-fed baby may be affected.

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 ETOPOPHOS may interfere with each other. These include:

- Levamisol (Ergamisol) a medicine that is used to treat some other forms of cancer

- Cyclosporin a medicine used to prevent rejection of transplanted organs

These medicines may be affected by ETOPOPHOS, 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.

Your doctor may have more information on medicines to be careful with or avoid while taking ETOPOPHOS.

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

How ETOPOPHOS is given

How much is given

Your doctor will decide what dose you will receive. Your dose of ETOPOPHOS injection 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.

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

Several courses of ETOPOPHOS 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 ETOPOPHOS you receive.

How is it given

ETOPOPHOS must only be prepared and administered by a doctor or nurse.

ETOPOPHOS injection is given as an infusion (drip) into your veins, over 5 minutes to 3.5 hours.

How long it is given

ETOPOPHOS 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. ETOPOPHOS may be given at the same time as other anti-cancer agents on days 1, 3 and 5 every 3 to 4 weeks.

Overdose

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

Symptoms of overdose may include, kidney failure, liver failure, failure of the immune system, and inflammation and ulceration of the mouth and stomach. .

While you are using ETOPOPHOS

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 ETOPOPHOS 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 having ETOPOPHOS.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking ETOPOPHOS.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking ETOPOPHOS.

If you become pregnant while having ETOPOPHOS, tell your doctor.

ETOPOPHOS 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.

Things you must not do

Do not drink alcohol while taking ETOPOPHOS.

You may feel flushed or get headaches.

Things to be careful of

Be careful driving or operating machinery until you know how ETOPOPHOS affects you.

As with other medicines used to treat cancer, ETOPOPHOS may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to ETOPOPHOS 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 or nurse as soon as possible if you do not feel well while you are having ETOPOPHOS.

Like other medicines that treat cancer, ETOPOPHOS 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 to answer any questions you may have.

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

These are the more common side effects of ETOPOPHOS.

- nausea, vomiting or diarrhoea
- loss of appetite, sore mouth
- stomach pain, constipation, altered taste
- unusual hair loss or thinning
- dizziness, light headedness
- feeling tired or weak
- problems swallowing
- low/high blood pressure

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
- sore mouth, eye pain, vision problems
- burning, stinging, pain, redness or swelling at the injection site
- kidney problems when high doses are given which is usually reversible

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following signs of a sudden life-threatening allergic reaction:

- chills, fever, fast heartbeat, wheezing or coughing, difficulty breathing, dizziness, flushing, sweating and swelling of the face, tongue or other parts of the body.

Other side effects not listed above may occur in some patients. Tell your doctor or nurse if you notice anything that is making you feel unwell.

After using ETOPOPHOS

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

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

Storage

ETOPOPHOS will be stored at the Clinic where you are being treated. Unopened vials of ETOPOPHOS injection should be stored in the refrigerator (2-8°C) and protected from the light.

Product description

What it looks like

ETOPOPHOS is a white to off-white powder in a glass vial.

Ingredients

Active: The active ingredient in ETOPOPHOS Injection is etoposide phosphate.

Inactive: Each vial also contains sodium citrate and Dextran 40.

Sponsored by

Bristol-Myers Squibb Australia Pty Ltd,

4 Nexus Court, Mulgrave,

Victoria 3170, Australia

Australian Registration Numbers:

ETOPOPHOS Injection (equivalent to 100mg etoposide) -
AUST R 57483

ETOPOPHOS Injection (equivalent to 500mg etoposide) -
AUST R 77219

ETOPOPHOS Injection (equivalent to 1g etoposide) - AUST
R 77220

Date of Preparation: May 2019

Further Information

Your doctor is the best person to answer any further questions you may have about ETOPOPHOS. You should follow any instructions given by your doctor.

Please note that knowledge about the safety of all medicines may change over time. You should discuss any problems you experience with ETOPOPHOS at any time with your doctor.

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