

ETHYOL®

amifostine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ETHYOL. It does not contain all of 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 being given ETHYOL against the benefits it is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What ETHYOL is used for

ETHYOL is used to protect you from some of the side effects caused by radiation therapy and drugs used to treat cancer such as cyclophosphamide, mitomycin-C and platinum-containing drugs. By reducing the risk of experiencing these side effects, it may increase your likelihood to continue or complete your chemotherapy regimen.

ETHYOL does not treat cancer.

Since anti-cancer drugs can reduce the number of white blood cells in your body, you may get an infection or fever. ETHYOL helps prevent you from getting infection and fever following the administration of certain anti-cancer drugs.

ETHYOL is also used to protect the kidneys from being damaged during

treatment with platinum-containing drugs.

ETHYOL can reduce the risk and severity of a side effect called xerostomia in patients receiving radiation therapy for cancer to the head and neck. Xerostomia causes the mouth to be very dry and often painful which can affect speech and eating.

Your doctor, however, may prescribe ETHYOL for another purpose.

Ask your doctor if you have any questions about why ETHYOL has been prescribed for you.

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

Before you are given ETHYOL

When you must not be given it

Do not use ETHYOL if:

- you are allergic to ETHYOL (amifostine) or aminothiols compounds
- you have low blood pressure
- you are pregnant or breastfeeding
- you are dehydrated
- you are a child or an adult older than 70 years of age.

Symptoms of allergic reaction may include:

- 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.

Before you are given it

You must tell your doctor if:

- you have kidney or liver problems
- you have low blood calcium levels
- you have problems with your blood pressure
- you suffer from heart or circulation problems, or have suffered from a stroke. Your doctor will monitor your blood pressure during treatment.
- you have any skin rashes or redness. Your doctor will check your skin before each treatment with ETHYOL.
- you have experienced any side effects in the past when given a thiol-containing compound as there could be an increased risk of experiencing side-effects with ETHYOL including severe skin reactions.

Low blood pressure may occur while you are being given ETHYOL. Your doctor may want you to drink extra fluids or give you some fluid through your veins to help prevent low blood pressure.

Your doctor may give you medicine to stop vomiting before you are given ETHYOL and while you are being treated with ETHYOL.

Taking other medicines

Tell your doctor if you are taking medicines to treat high blood pressure or low blood calcium levels.

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

The dose of some medications may have to be adjusted while you are being treated with ETHYOL.

If you are taking medicine to reduce blood pressure, your doctor may tell you to stop taking your blood pressure medicine 24 hours before you are given ETHYOL.

How ETHYOL is given

Treatment with ETHYOL should only be carried out under the supervision of your doctor or nurse.

The dose you are given depends on your weight and height. The dose also depends on what you are being treated for. Your doctor will work out the correct dose for you.

ETHYOL is administered by intravenous infusion (drip into your vein) by a medical or nursing professional.

Your doctor will determine how often you will be given ETHYOL. Your dose may be adjusted by your doctor during therapy according to your response.

Never try to inject ETHYOL yourself.

How long you will be given it

Your doctor will determine when your treatment should be stopped.

While you are given ETHYOL

Things you must do

Tell your doctor immediately if you develop a skin rash or hives or if you experience any difficulties breathing while you are being given ETHYOL.

Tell all doctors, dentists and pharmacists who are treating you that you are being treated with ETHYOL.

Things to be careful of

Low blood pressure may occur while you are being given ETHYOL.

If you feel faint or dizzy, do not drive a car or operate machinery.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given ETHYOL.

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

Ask your doctor or pharmacist any questions you may have.

During the infusion of ETHYOL the following reactions may occur:

- nausea or feeling sick
- vomiting
- low blood pressure, dizziness

Sometimes the ETHYOL drip may have to be stopped if your blood pressure is low.

During the infusion of ETHYOL, severe allergic reactions have also been reported. Symptoms include:

- high temperature
- feeling of coldness
- shivering, fever
- chest pain or discomfort
- skin rashes, redness, hives or itchy skin
- wheezing, shortness of breath, throat tightness or other breathing difficulties
- rare reports of anaphylaxis
- cardiac arrest

Tell your doctor or nurse immediately if you have any symptoms of allergic reaction.

Severe skin rashes that require ETHYOL treatment to be stopped and hospitalisation have been reported.

Tell your doctor immediately if you notice any of the following symptoms:

- skin rashes
- skin reactions such as redness, swelling of the skin, target-like spots, blisters and ulceration of the skin, mouth, throat, eyes or genitals.

The skin rashes can involve large areas of the skin and can often be accompanied by flu-like symptoms, skin pain, joint pain, fever and dehydration. They can sometimes result in death.

These symptoms may require immediate medical attention.

Other side effects may include:

- reactions at the site of injection including: rash, redness, itch, hives, bruising, pain, local swelling, and inflammation of the skin and vein
- changes in heart rate
- high blood pressure
- flushing, feeling of warmth
- feeling of coldness or chills
- sleepiness
- hiccups
- sneezing
- cough
- blurred or double vision
- seizures (convulsions) or fits
- loss of consciousness
- low calcium levels in your blood
- diarrhoea

This is not a complete list of side effects. Other side effects not listed above may also occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you unwell.

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

You may not experience any of them.

After ETHYOL has been stopped

Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with ETHYOL:

- feeling sick or vomiting
- low blood pressure, dizziness
- development of a rash or skin redness

Tell your doctor if you notice any other effects.

Storage

ETHYOL should be stored at a temperature below 25°C. Do not use beyond the expiration date.

Product description

What it looks like

ETHYOL Powder for Injection is a white powder. It is mixed with a sodium chloride solution before it is given to you.

Ingredients

Each vial of ETHYOL contains 500 mg of amifostine. There are no other ingredients in the vial.

Supplier

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Australian Registration Number
AUST R 63789

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