

# ETHYOL<sup>®</sup>

Amifostine

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## Consumer Medicine Information

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### What is in this leaflet

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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 taking 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 want to read it again.

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### What ETHYOL is used for

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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.

Since these 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 from these drugs.

ETHYOL is also used to protect the kidneys from being damaged during treatment with platinum-containing drugs.

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.**

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### Before you are given ETHYOL

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*When you must not be given it*

**Do not use ETHYOL if:**

1. **you are allergic to ETHYOL (amifostine)**
2. **you have low blood pressure**
3. **you are pregnant or breastfeeding**
4. **you are dehydrated**

**ETHYOL should not be used in children or in adults older than 70 years of age.**

*Before you are given it*

**You must tell your doctor if:**

1. **you have kidney or liver problems**
2. **you have low blood calcium levels**
3. **you have problems with your heart or blood vessels in your brain**

Your doctor will check your skin for any redness or rashes before each treatment with ETHYOL.

Your doctor may want you to drink extra fluids 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.

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### How ETHYOL is given

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ETHYOL is only available with a doctor's prescription. Treatment with ETHYOL should only be carried out under the supervision of your doctor.

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 this medicine yourself.**

### *How long you will be given it*

Your doctor will determine when your treatment should be stopped.

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## While you are given ETHYOL

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### *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*

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

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## Side effects

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**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:

- feeling sick or vomiting
- allergic reactions
- low blood pressure

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

**Tell your doctor or nurse immediately if you have an allergic reaction such as skin rashes, hives, wheezing, throat tightness or other breathing difficulties.**

These symptoms may require immediate medical attention.

Other side effects may include:

- changes in heart rate
- chest tightness or pain
- high blood pressure
- flushing
- feeling of warmth, fever
- feeling of coldness or chills
- dizziness
- sleepiness
- hiccups
- sneezing
- skin reactions
- convulsions or fits
- low calcium levels in your blood

Other side effects not listed above may also occur in some patients.

**Tell your doctor if you notice any other side effects.**

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

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## After ETHYOL has been stopped

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**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

**Tell your doctor if you notice any other effects**

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## Storage

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

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## Product description

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### *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*

Active ingredient: Amifostine

There are no other ingredients.

ETHYOL is available as a single vial containing 500 mg of amifostine.

### *Supplier*

#### In Australia:

Schering-Plough Pty Limited  
Level 4, 66 Waterloo Road  
North Ryde NSW 2113  
AUSTRALIA

#### In New Zealand:

Schering-Plough a division of  
Schering-Plough Animal Health  
Limited  
36 Kitchener Street  
Auckland  
New Zealand  
Phone: (09) 375 9210

### *Australian Registration Number*

AUST R 78720 (375mg)\*  
AUST R 63789 (500mg)

### *Date of Preparation*

13 June 2008

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\* not marketed