

Antizol

Fomepizole Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about Antizol. It does not contain all the information that is known about Antizol.

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

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

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

Keep this leaflet.

You may need to read it again.

What Antizol is used for

Antizol belongs to a group of medicines called antidotes.

Antizol is used to treat ethylene glycol and methanol poisoning.

Antizol helps to restore your blood levels of ethylene glycol and/or methanol to normal.

Your doctor may have administered this medicine for another reason.

Your doctor will explain why you are being treated with Antizol and tell you what dose you are being given.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you have any questions about why Antizol has been administered to you.

Antizol is not addictive.

This medicine is available only with a doctor's prescription

Before you are given Antizol

When you must not be given it

You must not be given Antizol if you have been drinking alcohol excessively.

You should not be given Antizol if you have ever experienced an anaphylactic reaction with Antizol or other pyrazoles.

Antizol should not be used if the expiry date (EXP) printed on the pack has passed.

Before you use it

Tell your doctor if you are pregnant or planning to become pregnant

The effect of ANTIZOL in pregnant women is not known. Therefore the use of ANTIZOL in pregnant women is not recommended.

Tell your doctor if you are breastfeeding or plan to breastfeed.

It is not known whether ANTIZOL passes into breast milk. If you are breast feeding, your doctor may advise you to stop breastfeeding while you are using this medicine.

Taking other medicines

Antizol can significantly reduce the rate of elimination of ethanol and

vice versa. For this reason, you should not be given Antizol if you have been drinking alcohol to excess.

Antizol may interact with medicines that increase or decrease the effect of phenytoin, carbamazepine, cimetidine, ketoconazole and other similar medicines, although this has not been studied.

How Antizol is given

Antizol is given as a slow intravenous infusion into a vein.

Antizol must only be given by a doctor or nurse.

Your doctor will decide what dose and for how long you will receive Antizol. This depends on your condition and other factors.

To begin treatment, 15 mg/kg of Antizol is given as a slow intravenous infusion over 30 minutes.

Your serum levels of ethylene glycol and/or methanol will be monitored during the treatment.

If you are given too much

The doctor giving you Antizol will be experienced in administration of antidotes, so it is unlikely that you will be given an overdose.

However, if you are accidentally given an overdose of Antizol, you may have nausea, dizziness or vertigo. These are usually short-lived.

Your doctor has information on how to recognise and treat an

overdose. Ask your doctor if you have any concerns.

Side Effects

Tell your doctor as soon as possible if you do not feel well while you are being given Antizol.

Antizol helps most people with ethylene glycol and/or methanol intoxication, but it may have unwanted side effects in a few people.

If you are over 65 years of age you may have an increased chance of getting side effects.

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

If you have any questions, please talk to your doctor, nurse or pharmacist.

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

- Hangover
- Light-headedness
- Dizziness
- Feeling drunk
- Facial flush
- Speech/visual disturbances, including temporary blurred vision
- Abdominal pain
- Fever
- Back pain
- Pain or burning along the length of a vein
- Vein being hard and cord like
- Fainting
- Seizures
- Nausea or vomiting
- Diarrhoea
- Indigestion
- Heartburn

- Decreased appetite
- Agitation/anxiety
- Pharyngitis
- Rash
- Abnormal smell
- Roar in ear
- Headache
- Drowsiness
- Bad or metallic taste
- Cough
- Vertigo
- Sweating or feeling of warmth
- Rapid involuntary eye movements
- Heart rate increase or decrease
- Blood pressure increase or decrease
- Confusion

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

- Signs of kidney problems such as painful urination, difficulty urinating or lower back pain
- Signs of anaemia such as paleness, coldness, clamminess or fatigue
- Easy bruising

The above list includes serious side effects, which may require medical attention.

If any of the following happen, tell your doctor or nurse immediately, or go to emergency department at your nearest hospital:

- Signs of an allergic reaction, such as 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

Some people may get other side effects while being given Antizol that are not present on this list.

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

After being given Antizol

Storage

Antizol will be stored in the pharmacy ward.

Product is for single use in one patient only. Discard any residue.

The injection is kept in a cool, dry place, protected from light, where the temperature stays below 25°C.

Product Description

What Antizol looks like

Antizol is a clear to yellow liquid at room temperature. It may present as a solid at lower temperatures.

Ingredients

Each vial of Antizol contains 1.5 g of fomepizole. The vials are packed under nitrogen but do not contain any other excipients.

Sponsor

In Australia

AFT Pharmaceuticals Pty Ltd
113 Wicks Road
North Ryde
NSW 2113

In New Zealand

AFT Pharmaceuticals Ltd,
Auckland.

Australian Registration Number
AUST R 263913

This leaflet was prepared in
November 2016