Package leaflet: Information for the user

Fomepizole Waymade 1 g/ml concentrate for solution for infusion
fomepizole

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fomepizole Waymade is and what it is used for

Fomepizole Waymade is a medicine which contains the active ingredient fomepizole.

Fomepizole is indicated as an antidote for ethylene glycol (antifreeze) poisoning in patients who have swallowed or are suspected of having swallowed ethylene glycol.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you use Fomepizole Waymade

Do not use Fomepizole Waymade:
- If you are allergic to fomepizole or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to other medicines belonging to the same family (pyrazoles). In such case, you may also be allergic to fomepizole.

Warnings and precautions

Take special care with Fomepizole Waymade
- If you experience:
  - a sudden swelling of the throat, face, lips or mouth,
  - redness, skin rash or itching.

It is an allergic reaction. In this case, your doctor will monitor the observed signs.
If your allergic reaction becomes more important or gets worse, you should immediately stop your treatment in absence of any other obvious cause.

- If you have liver problems (impaired liver function). In this situation, your doctor will ask you to perform blood test in order to monitor your liver function.

Talk to your doctor before using Fomepizole Waymade:

Other medicines and Fomepizole Waymade
You should not combine medicines containing alcohol and Fomepizole Waymade. It may reduce their elimination.
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Pregnancy and breast-feeding
You should not use fomepizole if you are pregnant or if you are breast-feeding unless absolutely necessary.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
You should not drive or use any tools or machines the first few days after treatment is discontinued.
Dizziness and vertigo may occur after treatment. If you experience any of these signs, you should not drive or use any tools or machines.

3. How to use Fomepizole Waymade

Dosage
This medicine will be given by your doctor. It will be given to you as a slow injection into one of your veins.

The dose of fomepizole varies from one patient to another. Your doctor will decide the correct dose.

It depends on:
- your age, your weight,
- how your liver and kidneys are working,
- if you need a medical procedure for removing ethylene glycol from your blood (also called hemodialysis).

If you have been given more Fomepizole Waymade than you should, the following effects may occur:
• dizziness,
• drunkenness,
• feeling sick (nausea),
• vertigo,
• headaches,
• blurred vision,
• slurred speech.

If you experience any of these signs, you should contact your doctor immediately.

In these circumstances your doctor may decide to undertake a medical procedure called hemodialysis which will remove excess drug from blood.

If you forget to use Fomepizole Waymade

Take the next dose as usual. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them.

The most commonly adverse effects are:
• Dizziness,
• Headaches.

The following side effects may commonly occur:
• Allergic reactions.
- In administration area: injection site reaction, injection site inflammation.
- Skin: a sudden swelling of the throat, face, lips or mouth, redness, skin rush or itching.

If you experience any of these signs, you should tell your doctor.
He/she will monitor the observed signs.
If your allergic reaction becomes more important or gets worse, you should immediately stop your treatment in absence of any other obvious cause.

Other side effects that may occur with Fomepizole Waymade:
• Heart and circulation:
- abnormal pulse rate,
- strong heart beat.

• Nervous system:
- vertigo,
- anxiety, agitation,
- blurred vision, vision disorders,
- fits (convulsions),
- slurred speech.

• Stomach and gut:
- feeling sick (nausea), being sick (vomiting),
- diarrhoea, indigestion (dyspepsia),
- hiccups.

• Alteration in the blood:
- temporary increase of liver enzymes (test done to check liver function),
- increased blood pressure,
- increased CPK (test done to check muscular function),
- increase in some white blood cells count (eosinophils),
- decrease in red cells (anaemia).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Fomepizole Waymade

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

After dilution
Chemical and physical in-use stability has been demonstrated in 5% dextrose and 0.9% sodium chloride solutions for 72 hours at 2 to 8°C and 25°C.

From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Do not use this medicine after the expiry date which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Fomepizole Waymade contains
The active substance is fomepizole (Each ml of solution contains 1 g of fomepizole. Each 1.5 ml vial contains 1.5 g of fomepizole). There is no other ingredient in Fomepizole Waymade.

What Fomepizole Waymade looks like and contents of the pack
Fomepizole Waymade is a clear to yellow liquid at room temperature. It may present as solid form at temperature less than 25°C.

It is available in clear glass vial packed in a carton containing 1 vial each. Each vial contains 1.5 ml (1 g/ml) of fomepizole.

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The following information is intended for healthcare professionals only:
The treatment should begin whenever ethylene glycol poisoning is suspected, as early as possible after its ingestion, even in absence of signs of toxicity.

Dosage
In the absence of ethylene glycol assay, ethylene glycol poisoning should be suspected on the following criteria:
• patient's history,
• osmolar gap > 20 mOsm/kg H20,
• metabolic acidosis with anion gap > 16 mmol/l (presence of high levels of glycolates),
• calcium oxalate crystals in the urine.

An assay for plasma ethylene glycol should be performed at admission, but this determination should

not delay start of treatment with Fomepizole Waymade. Plasma ethylene glycol levels should be monitored every 12 to 24 hours.

Fomepizole Waymade must be diluted before use and administered by slow intravenous infusion.
The concentrate should be diluted with 0.9% sodium chloride solution or 5% dextrose solution for intravenous use.

Dosage depends on plasma ethylene glycol concentration, renal function and on body weight.

Patients with normal renal or mild to moderate impaired renal function as assessed by serum creatinine (100 to 265 µmol/l) in whom hemodialysis is not required:

Administration should be performed by slow intravenous infusion, over 30 to 45 minutes, given as follows: infusion of a loading dose of 15 mg/kg followed by doses every 12 hours until ethylene glycol levels have been reduced (below 0.2 g/l (3.2 mmol/l)).

Fomepizole dose (mg/kg body weight)					
loading dose	2nd dose (12 hours)	3rd dose (24 hours)	4th dose (36 hours)	5th dose (48 hours)	6th dose (60 hours)
15	10	10	10	7.5 to 15	5 to 15

The number of maintenance doses and the dose after 48 hours will depend on initial concentration and the time course of the ethylene glycol levels.

Generally, 4 to 5 maintenance doses are recommended for initial ethylene glycol levels between 3 to 6 g/l (48 to 96 mmol/l) and 1 to 3 maintenance doses are recommended for initial ethylene glycol levels between 0.35 to 1.5 g/l (5.6 to 24 mmol/l).

Patients with severe impaired renal function as assessed by serum creatinine (> 265 µmol/l):
Hemodialysis is indicated in combination with Fomepizole Waymade.
Hemodialysis and fomepizole administration should be discontinued when the metabolic acidosis is corrected and plasma ethylene glycol levels have been reduced below 0.2g/l (3.2 mmol/l).
A loading dose of 15 mg/kg is infused over 30 to 45 minutes, followed by 1 mg/kg/hour continuous infusion for the entire duration of the hemodialysis.
Hemodialysis should also be initiated under at least one of the following features in combination with fomepizole:
• arterial pH < 7.10,
• drop in arterial pH > 0.05 resulting in a pH outside the normal range despite bicarbonate infusion,
• inability to maintain arterial pH > 7.30 despite bicarbonate therapy,
• decrease in serum bicarbonate concentration of more than 5 mmol/l despite bicarbonate therapy,
• rise in serum creatinine by > 90 µmol/l (1 mg/dl).

Elderly patients
Clinical experience in elderly patients is limited. The regimen has to be adjusted to the renal function (see above).

Children
There is no available data regarding the pharmacokinetics of fomepizole in children. Clinical experience is limited and based on similar weight-adjusted doses.

Instructions for preparation for infusion

For single use only. Any unused product must be discarded.

Fomepizole solidifies at temperature less than 25°C. If the fomepizole solution has become solid in the vial the solution should be liquefied by running the vial under warm water or holding in the hand. Solidification does not affect the efficacy, safety or stability of fomepizole.

Fomepizole Waymade is to be diluted before use.
Fomepizole Waymade, should not be given undiluted; the diluted concentrate should not be given by bolus injection.

This medicinal product must not be mixed with other medicinal products.
Preparation of solution for infusion must take place in aseptic conditions.

The concentrate should be diluted with 0.9 % sodium chloride solution or 5 % dextrose solution for intravenous use:

- in patient with normal renal function: each single dose will be diluted with 100 to 250 ml of the above solutions and infused over 30 to 45 minutes.
- in patient with impaired renal function: for continuous infusion in patient undergoing hemodialysis, the concentrate may exceptionally be diluted in a reduced volume of the above solutions, in order to avoid fluid overload.

Chemical and physical in-use stability has been demonstrated in 5% dextrose and 0.9% sodium chloride solutions for 72 hours at 5°C and 25°C.

From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Compatibility/ Incompatibility with Containers:
Avoid polycarbonate syringes or polycarbonate containing needles (including polycarbonate filter needles) when diluting or administering fomepizole. Fomepizole can interact with polycarbonate, compromising the integrity of the syringe and/or needle component containing polycarbonate.