

TERLIPRESSIN EVER PHARMA

Solution for Injection

(Terlipressin)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TERLIPRESSIN EVER PHARMA.

It does not contain all of the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What TERLIPRESSIN EVER PHARMA is used for

TERLIPRESSIN EVER PHARMA contains terlipressin.

TERLIPRESSIN EVER PHARMA is used to treat Bleeding Oesophageal Varices (BOV), bleeding veins in the lower end of the food-pipe in people with serious liver disease. When the liver is diseased, there is less blood flowing through it. This causes the blood to 'back up' in the veins in the lower end of the food pipe (and upper part of the stomach). The veins in the lining of the food pipe (and stomach) then become very large and stretched, much like varicose

veins. Because the veins are also very fragile, they can rupture and then bleed severely into the stomach.

TERLIPRESSIN EVER PHARMA contains terlipressin, a substance which acts to stop the bleeding by lowering the blood pressure in the veins of the foodpipe.

TERLIPRESSIN EVER PHARMA is also used to treat hepatorenal syndrome, type 1 (HRS-1).

TERLIPRESSIN EVER PHARMA is given when a patient with HRS-1 is being considered for a liver transplant. HRS-1 is a condition in which the kidneys suddenly fail to work in a person with severe liver disease. HRS-1 is a life-threatening complication of severe liver disease.

The cause of HRS-1 is not fully understood. It is thought to be due to the kidneys drastically reducing their own blood flow, in response to large changes in blood flow in other parts of the body caused by severe liver disease.

TERLIPRESSIN EVER PHARMA works in HRS-1 by improving the blood flow in the kidneys.

Ask your doctor if you have any questions about why TERLIPRESSIN EVER PHARMA has been prescribed for you.

Your doctor may have prescribed it for another reason.

TERLIPRESSIN EVER PHARMA is not addictive.

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

Before you are given TERLIPRESSIN EVER PHARMA

When you must not be given it

Do not use TERLIPRESSIN EVER PHARMA if you have an allergy to terlipressin, the active ingredient, or to any of the other ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to TERLIPRESSIN EVER PHARMA 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.

Do not use TERLIPRESSIN EVER PHARMA if you are pregnant.

It may affect your developing baby if you are given it during pregnancy.

Do not use TERLIPRESSIN EVER PHARMA if you are breast-feeding or planning to breast-feed.

It is not known if it passes into breast milk or is safe for use in infants.

Do not use TERLIPRESSIN if you currently have heart disease or have recently had heart disease.

Do not use TERLIPRESSIN EVER PHARMA after the expiry date (EXP) printed on the pack.

If you use it after the expiry date has passed, it may not work as well.

Do not use TERLIPRESSIN EVER PHARMA if the packaging is torn/damaged/ or show signs of tampering.

Before you are given it

Tell your doctor if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart disease
- history of heart attack
- high blood pressure
- irregular heartbeat
- circulation problems
- kidney problems
- Asthma or respiratory problems
- you are on a controlled sodium diet (this medicine contains 1.33 mmol (or 30.7 mg) of sodium per vial)

Tell your doctor if you plan to have surgery. If you have not told your doctor about any of the above, tell them before you start taking TERLIPRESSIN EVER PHARMA.

Taking other medicines

Tell your doctor or Pharmacist 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 TERLIPRESSIN EVER PHARMA may interfere with each other. These include:

- beta blockers - used to treat high blood pressure and certain heart conditions

- propofol, a short-acting anaesthetic
- sufentanil, a powerful opioid painkiller (not available in Australia).
- erythromycin, an antibiotic
- medicines used to control heart rhythm such as amiodarone
- some antidepressants, such as amitriptyline

Taking TERLIPRESSIN EVER PHARMA with these medicines may cause your heart to slow down or beat irregularly.

These medicines may be affected by TERLIPRESSIN EVER PHARMA, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and Pharmacist may have more information on medicines to be careful with or avoid while taking TERLIPRESSIN EVER PHARMA.

How TERLIPRESSIN EVER PHARMA is given

How much you will be given

TERLIPRESSIN EVER PHARMA is a medicine that is used in hospital and should only be administered by your doctor or nurse.

Your doctor will give you the correct amount of TERLIPRESSIN EVER PHARMA.

Your doctor may adjust the dose depending on how you are responding to the treatment.

The maximum dose is 1.7 mg every 4 hours (BOV) or every 6 hours (HRS-1). Instructions for proper use of the drug intended for your doctor or nurse are included in the package insert.

How it is given

TERLIPRESSIN EVER PHARMA will be given to you by injection in one of your veins.

How often it is given

TERLIPRESSIN EVER PHARMA is usually given for up to 48 hours BOV.

TERLIPRESSIN EVER PHARMA is generally used for up to 2 weeks or less in treating an occurrence of HRS-1.

If you are given too much (overdose)

As TERLIPRESSIN EVER PHARMA is given to you by a nurse and under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience any side effects after you are discharged, immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you receive too much TERLIPRESSIN EVER PHARMA, you may experience any of the following:

- headache
- pale skin
- blue lips and fingernails
- stomach pain or discomfort
- nausea
- diarrhoea.

While you are using TERLIPRESSIN EVER PHARMA

Things you must do

Tell any other doctors, dentists, and Pharmacists who are treating you that you are or have been treated with TERLIPRESSIN EVER PHARMA.

If you are about to be started on any new medicine, tell your doctor, dentist or Pharmacist that you are or have been treated with TERLIPRESSIN EVER PHARMA.

Be sure to keep all your doctor's appointments.

Your doctor will want to do blood and other tests regularly to check on your progress and detect any unwanted side effects.

If you become pregnant while you are being given this medicine, stop taking/using it and tell your doctor, nurse or Pharmacist immediately. If you are breastfeeding or if you plan to breastfeed while you are given this medicine, tell your doctor.

Things that may help your condition

Some self-help measures suggested below may help your condition.

Talk to your doctor or Pharmacist about them:

- alcohol - your doctor may advise you to limit your alcohol intake
- diet - eat a healthy diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar
- smoking - your doctor may advise you to stop smoking or at least cut down.

Side effects

Tell your doctor or nurse immediately if you do not feel well after you have TERLIPRESSIN EVER PHARMA.

Like all medicines, TERLIPRESSIN EVER PHARMA can have side effects, although not everybody gets them. Sometimes the side effects can be serious, although most of the time they are not. You may need medical attention if you get some of the side effects.

The hospital staff will be monitoring you for possible side effects. If you get some of the side effects, your doctor and/or nurse will help you manage them while you are in the hospital. Ask your doctor, nurse or Pharmacist to answer any questions you may have.

Don't be alarmed by the following list of side effects. You may not experience any of them.

The most frequently reported side effects are:

- headache
- increased blood pressure
- slow, fast or irregular heart beat
- pale skin
- blue lips and fingernails
- stomach pain or discomfort
- diarrhoea.

Other side effects include:

- local irritation at the injection site
- difficulty breathing
- hot flushes
- chest pain
- heart failure
- feeling or being sick (nausea or vomiting)
- swelling due to excess fluid in the Body

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

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

After using TERLIPRESSIN EVER PHARMA

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor, nurse or Pharmacist.

Product description

What it looks like

TERLIPRESSIN EVER PHARMA is given as intravenous injection:

Solution for Injection

Clear colourless aqueous solution,
- 5 mL of injection solution contains 1 mg terlipressin acetate equivalent to 0.85 mg terlipressin.
- 10 mL of injection solution contains 2 mg terlipressin acetate equivalent to 1.7 mg terlipressin.

Each mL contains 0.17 mg terlipressin equivalent to 0.2 mg terlipressin acetate.

Ingredients

Active ingredient:

The active ingredient in TERLIPRESSIN EVER PHARMA preparations is terlipressin.

Other ingredients:

Sodium chloride

Acetic acid

Sodium hydroxide (for pH-adjustment)

Hydrochloric acid (for pH-adjustment)

Water for injections.

Supplied in colourless glass vials,
closed with rubber stopper and
sealed with aluminium flip-off cap.

Each vial contains 5 mL or 10 mL
of solution.

Pack sizes:

1 x 5mL, 5 x 5mL

1 x 10mL, 5 x 10mL

Storage conditions

Store at 2°C to 8°C (Refrigerate. Do
not freeze). Store in the outer carton
to protect from light.

Sponsor

InterPharma Pty Ltd,
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Australian Registration Numbers

1 x 5mL, 5 x 5mL – AUST R
288142

1 x 10mL, 5 x 10mL – AUST R
288156

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