

# TERLIPRESSIN EVER PHARMA

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I being given TERLIPRESSIN EVER PHARMA?

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. TERLIPRESSIN EVER PHARMA is also used to treat hepatorenal syndrome, type 1 (HRS-1) when a patient with HRS-1 is being considered for a liver transplant. HRS-1 is a life-threatening complication in which the kidneys suddenly fail to work in a person with severe liver disease. TERLIPRESSIN EVER PHARMA contains the active ingredient terlipressin, which is similar to the hormone vasopressin.

For more information, see Section [1. Why am I being given TERLIPRESSIN EVER PHARMA?](#) in the full CMI.

### 2. What should I know before being given TERLIPRESSIN EVER PHARMA?

Do not use TERLIPRESSIN EVER PHARMA if you have ever had an allergic reaction to terlipressin, or to any of the ingredients listed at the end of the CMI. (see Section [7. Product details](#) in the full CMI.)

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before being given TERLIPRESSIN EVER PHARMA?](#) in the full CMI.

### 3. What if I am taking other medicines?

**Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines may interfere with TERLIPRESSIN EVER PHARMA and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How will I be given TERLIPRESSIN EVER PHARMA?

- 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.
- Instructions for proper use of the drug intended for your doctor or nurse are included in the package insert.

More instructions can be found in Section [4. How will I be given TERLIPRESSIN EVER PHARMA?](#) in the full CMI.

### 5. What should I know while being given TERLIPRESSIN EVER PHARMA?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell any doctor, dentist or pharmacist you visit that you are being given TERLIPRESSIN EVER PHARMA.</li><li>• 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.</li><li>• If you become pregnant while you are being given this medicine, stop taking/using it and tell your doctor, nurse or pharmacist immediately.</li></ul>
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For more information, see Section [5. What should I know while being given TERLIPRESSIN EVER PHARMA?](#) in the full CMI.

### 6. Are there any side effects?

All medicines can have side effects. Most of them are minor and temporary but some may need medical attention.

**Tell your doctor if you experience any side effects including rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing, abnormal heart rhythm and fatigue which may result in developing serious life-threatening conditions (e.g. heart attack). These are very serious side effects. You may need urgent medical attention.**

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# TERLIPRESSIN EVER PHARMA

Active ingredient: *terlipressin* (as *terlipressin acetate*)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using TERLIPRESSIN EVER PHARMA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TERLIPRESSIN EVER PHARMA.**

**Where to find information in this leaflet:**

- [1. Why am I being given TERLIPRESSIN EVER PHARMA?](#)
- [2. What should I know before being given TERLIPRESSIN EVER PHARMA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given TERLIPRESSIN EVER PHARMA?](#)
- [5. What should I know while being given TERLIPRESSIN EVER PHARMA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being given TERLIPRESSIN EVER PHARMA?

TERLIPRESSIN EVER PHARMA is used in the treatment of Bleeding Oesophageal Varices (BOV) and in the treatment of hepatorenal syndrome, type 1 (HRS-1) when a patient with HRS-1 is being considered for a liver transplant.

TERLIPRESSIN EVER PHARMA contains the active ingredient terlipressin, which is similar to a natural human hormone vasopressin.

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 acts to stop the bleeding by lowering the blood pressure in the veins of the food-pipe.

TERLIPRESSIN EVER PHARMA is also given when a patient with hepatorenal syndrome, type 1 (HRS-1) is being considered for a liver transplant. HRS-1 is a life-threatening complication in which the kidneys suddenly fail to work in a person with 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.

## 2. What should I know before being given TERLIPRESSIN EVER PHARMA?

### Warnings

**TERLIPRESSIN EVER PHARMA should not be used if:**

- you are allergic to terlipressin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are pregnant or breastfeeding.
- you currently have heart disease or have recently had heart disease.

**Tell your doctor if you:**

- have or have had any other medical conditions, especially the following:
  - heart disease, including previous heart attack
  - high blood pressure
  - irregular heartbeat
  - blood circulation problems, including diseases affecting the blood vessels in the brain or limbs.
  - obesity
  - severe asthma or chronic obstructive pulmonary disease (COPD)
  - kidney problems
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

**Do not use TERLIPRESSIN EVER PHARMA if you are pregnant or breastfeeding.**

It may affect you and your developing baby if you use it during pregnancy. Talk to your doctor immediately if you become pregnant while using TERLIPRESSIN EVER PHARMA.

## 3. What if I am taking other medicines?

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

**Some medicines may interfere with TERLIPRESSIN EVER PHARMA and affect how it works.**

**Medicines that have their heart rate lowering effect increased when taken with TERLIPRESSIN EVER PHARMA include:**

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

- other medicines which slow your heart rate such as propofol, a short-acting anaesthetic.
- sufentanil, a powerful opioid painkiller (not available in Australia).

**TERLIPRESSIN EVER PHARMA may trigger irregular beating of the heart when taken with:**

- quinidine, procainamide, disopyramide (known as Class 1A anti-arrhythmic medicines)
- amiodarone, sotalol, ibutilide, dofetilide (known as Class III anti-arrhythmic medicines)
- erythromycin, an antibiotic
- medicines used to treat allergies and may also be found in certain cough and cold remedies (known as antihistamines)
- some anti-depressants (known as tricyclic antidepressants)
- medicines that may change the level of salt or electrolytes in your blood, such as diuretics or "fluid" medicines (medicines used to treat high blood pressure and heart failure).

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect or are affected by TERLIPRESSIN EVER PHARMA.**

#### **4. How will I be given TERLIPRESSIN EVER PHARMA?**

**How much you will be given**

- TERLIPRESSIN EVER PHARMA is a medicine that is used in hospital and should only be administered intravenously 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
- Instructions for proper use of the drug intended for your doctor or nurse are included in the package insert.

**When you will be given TERLIPRESSIN EVER PHARMA**

- When treating BOV, TERLIPRESSIN EVER PHARMA should not continue for more than 48 hours in total.
- When treating HRS-1, TERLIPRESSIN EVER PHARMA is usually used for 7-10 days (10 days on average).

**How TERLIPRESSIN EVER PHARMA is given**

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

#### **If you are given too much TERLIPRESSIN EVER PHARMA**

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, you should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26** in Australia and or New Zealand 0800 POISON in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

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

- increased blood pressure
- faster heart beats
- headache
- pale skin
- blue lips and fingernails
- stomach pain or discomfort
- nausea
- diarrhea.

#### **5. What should I know while being given TERLIPRESSIN EVER PHARMA?**

**Things you should do**

**Call your doctor straight away if you:**

- **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, tell your doctor, nurse or pharmacist immediately.**

Remind any doctor, dentist or pharmacist you visit that you have been given TERLIPRESSIN EVER PHARMA.

#### **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects*	
Side effects	What to do
<p><b>Very common side effects (affect more than 1 in 10 users):</b></p> <ul style="list-style-type: none"> <li>• difficulty breathing**</li> <li>• stomach (abdominal) pain or discomfort</li> </ul> <p><b>Common side effects (affect at least 1 in 100 and less than 1 in 10 users):</b></p> <ul style="list-style-type: none"> <li>• low blood sodium concentration</li> <li>• headache</li> <li>• chest pain</li> <li>• slow or fast heartbeat</li> <li>• constriction of blood vessels</li> <li>• pale skin</li> <li>• increased blood pressure</li> <li>• blueish colouration of skin and lips</li> <li>• difficulty breathing***</li> <li>• diarrhoea</li> <li>• nausea or vomiting</li> </ul> <p><b>Uncommon side effects (affect at least 1 in 1000 and less than 1 in 100 users):</b></p> <ul style="list-style-type: none"> <li>• abnormal heart rhythm</li> <li>• hot flushes</li> </ul> <p><b>Side effect with unknown frequency:</b></p> <ul style="list-style-type: none"> <li>• uterine constriction (constriction of the womb)</li> </ul>	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Serious side effects*	
Serious side effects	What to do
<p><b>Allergic reaction:</b></p> <ul style="list-style-type: none"> <li>• rash, itching or hives on the skin</li> <li>• swelling of the face, lips, tongue or other parts of the body</li> <li>• shortness of breath, wheezing or difficulty breathing</li> </ul> <p>Myocardial infarction, also known as a heart attack, is a condition when your heart muscle begins to die because it isn't getting enough blood flow (uncommon)</p> <p><b>Heart failure (uncommon)</b></p> <p>Respiratory failure is a condition when your lungs are not able to get enough oxygen into your blood (very common)**(uncommon)***</p> <p>Intestinal ischaemia is a condition when there is reduced blood flow to the intestines (uncommon)</p> <p>Uterine ischaemia is a condition where there is decreased blood flow to the uterus (frequency unknown)</p> <p>Sepsis/Septic shock is a condition when the body's immune response to an infection causes damage to its own tissue and organs (common)**</p> <p>Skin necrosis and injection site necrosis are conditions when skin tissue begins to die (uncommon)</p> <p>Severe and persistent irregular heart rhythm, including Torsade de Pointes (uncommon)</p> <p>Pulmonary oedema is a condition where there is excess fluid in the lungs (common)**</p>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

\*Side effects and how often they occur can depend on what you are being given TERLIPRESSIN EVER PHARMA for.

\*\* Applicable to HRS-1

\*\*\*Applicable to BOV

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) and/or Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines**

## 7. Product details

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

### What TERLIPRESSIN EVER PHARMA contains

<b>Active ingredient (main ingredient)</b>	terlipressin (as terlipressin acetate)
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride Glacial acetic acid Sodium hydroxide Hydrochloric acid Water for Injections

**Do not take this medicine if you are allergic to any of these ingredients.**

### What TERLIPRESSIN EVER PHARMA looks like

Clear colourless aqueous solution,

- 5 mL of injection solution contains 1 mg terlipressin acetate equivalent to 0.85 mg terlipressin. – AUST R 288142, File ref: TT50-10673

- 10 mL of injection solution contains 2 mg terlipressin acetate equivalent to 1.7 mg terlipressin– AUST R 288156, File ref: TT50-10673a

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

Pack sizes:

1 x 5mL, 5 x 5mL

1 x 10mL, 5 x 10mL

### Who distributes TERLIPRESSIN EVER PHARMA

#### In Australia:

InterPharma Pty Ltd,  
Suite 103,  
39 East Esplanade,  
Manly NSW 2095,  
Australia

#### In New Zealand:

Healthcare Logistics On behalf of InterPharma Pty Ltd  
58 Richard Pearse Drive  
Airport Oaks, Mangere 2022  
Auckland, New Zealand

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