

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 GLYPRESSIN?

GLYPRESSIN is used to treat Bleeding Oesophageal Varices (BOV) bleeding veins in the lower end of the food pipe in people with serious liver disease. GLYPRESSIN 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. GLYPRESSIN contains the active ingredient terlipressin, which is similar to the hormone vasopressin.

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

2. What should I know before being given GLYPRESSIN?

Do not use GLYPRESSIN 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 GLYPRESSIN?](#) 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 GLYPRESSIN 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 GLYPRESSIN?

- GLYPRESSIN 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 GLYPRESSIN. 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 GLYPRESSIN?](#) in the full CMI.

5. What should I know while being given GLYPRESSIN?

Things you should do	<ul style="list-style-type: none">• Tell any doctor, dentist or pharmacist you visit that you are being given GLYPRESSIN.• 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.
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For more information, see Section [5. What should I know while being given GLYPRESSIN?](#) 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.

GLYPRESSIN®

Active ingredient: terlipressin (as terlipressin acetate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using GLYPRESSIN. **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 GLYPRESSIN.**

Where to find information in this leaflet:

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

1. Why am I being given GLYPRESSIN?

GLYPRESSIN 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.

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

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

GLYPRESSIN 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. GLYPRESSIN works in HRS-1 by improving the blood flow in the kidneys.

2. What should I know before being given GLYPRESSIN?

Warnings

GLYPRESSIN 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.

Tell your doctor if you:

- have or have had any other medical conditions, especially the following:
 - o heart disease, including previous heart attack
 - o high blood pressure
 - o irregular heartbeat
 - o blood circulation problems, including diseases affecting the blood vessels in the brain or limbs
 - o obesity
 - o severe asthma or chronic obstructive pulmonary disease (COPD)
 - o kidney problems
 - o you are on a controlled sodium diet (this medicine contains 1.33 mmol (or 30.7 mg) of sodium per ampoule).
- 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 GLYPRESSIN 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 GLYPRESSIN.

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 GLYPRESSIN and affect how it works.

Medicines that have their heart rate lowering effect increased when taken with GLYPRESSIN 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).

GLYPRESSIN 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 GLYPRESSIN.

4. How will I be given GLYPRESSIN?

How much you will be given

- GLYPRESSIN 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 GLYPRESSIN
- 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 GLYPRESSIN

- When treating BOV, GLYPRESSIN should not continue for more than 48 hours in total.
- When treating HRS-1, GLYPRESSIN is usually used for 7-14 days.

How GLYPRESSIN is given

- GLYPRESSIN will be given to you by:
 - BOV: quick injection in one of your veins
 - HRS-1: quick injection in one of your veins or given slowly into a vein over a longer period.

If you are given too much GLYPRESSIN

As GLYPRESSIN 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**), 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 GLYPRESSIN, 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
- diarrhoea.

5. What should I know while being given GLYPRESSIN?

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 GLYPRESSIN.

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>Very common side effects (affect more than 1 in 10 users):</p> <ul style="list-style-type: none"> • difficulty breathing** • stomach (abdominal) pain or discomfort <p>Common side effects (affect at least 1 in 100 and less than 1 in 10 users):</p> <ul style="list-style-type: none"> • low blood sodium concentration • headache • chest pain • slow or fast heartbeat • constriction of blood vessels • pale skin • increased blood pressure • blueish colouration of skin and lips • difficulty breathing*** • diarrhoea • nausea or vomiting 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Side effects	What to do
<p>Uncommon side effects (affect at least 1 in 1000 and less than 1 in 100 users):</p> <ul style="list-style-type: none"> abnormal heart rhythm hot flushes <p>Side effect with unknown frequency:</p> <ul style="list-style-type: none"> uterine constriction (constriction of the womb) 	

Serious side effects*

Serious side effects	What to do
<p>Allergic reaction:</p> <ul style="list-style-type: none"> 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 <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>Heart failure (uncommon)</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>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.</p>

*Side effects and how often they occur can depend on what you are being given GLYPRESSIN 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. 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 GLYPRESSIN contains

Active ingredient (main ingredient)	terlipressin (as terlipressin acetate)
Other ingredients (inactive ingredients)	sodium chloride acetic acid sodium acetate trihydrate water for Injections

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

What GLYPRESSIN looks like

GLYPRESSIN is given as intravenous injection or intravenous infusion (for HRS-1 only) .

GLYPRESSIN is a clear and colourless solution in an ampoule, containing 8.5mL of GLYPRESSIN solution. It is supplied in a box containing 5 ampoules (AUST R 177708).

Who distributes GLYPRESSIN

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1

20 Bridge Street

Pymble NSW 2073

Australia

Toll free: 1800 337 746

GLYPRESSIN is a registered trademark of Ferring.

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