

GLYPRESSIN®

Solution for Injection

Terlipressin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about GLYPRESSIN.

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 GLYPRESSIN 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 GLYPRESSIN is used for

GLYPRESSIN contains terlipressin.

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 contains terlipressin, a substance which acts to stop the bleeding by lowering the blood pressure in the veins of the food-pipe.

GLYPRESSIN is also used to treat hepatorenal syndrome, type 1 (HRS-1). GLYPRESSIN 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.

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

Ask your doctor if you have any questions about why GLYPRESSIN has been prescribed for you.

Your doctor may have prescribed it for another reason.

GLYPRESSIN is not addictive.

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

Before you are given GLYPRESSIN

When you must not be given it

Do not use GLYPRESSIN 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 GLYPRESSIN 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 GLYPRESSIN if you are pregnant.

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

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

Do not use GLYPRESSIN 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 GLYPRESSIN if the packaging is torn/damaged or shows 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
- high blood pressure
- irregular heartbeat
- circulation problems
- kidney problems
- you are on a controlled sodium diet (this medicine contains 1.33 mmol (or 30.7 mg) of sodium per ampoule)

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 GLYPRESSIN.

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 GLYPRESSIN 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).

Taking GLYPRESSIN with these medicines may cause your heart to slow down or beat irregularly.

These medicines may be affected by GLYPRESSIN, 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.

Tell your doctor immediately if you take any of the following medicines:

Medicines that can trigger irregular beating of the heart (known as arrhythmia) such as:

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

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking GLYPRESSIN.

How GLYPRESSIN is given

How much you will be given

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.

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

GLYPRESSIN will be given to you by injection in one of your veins.

How often it is given

GLYPRESSIN is usually given for up to 48 hours BOV.

GLYPRESSIN 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 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, 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 GLYPRESSIN, you may experience any of the following:

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

While you are using GLYPRESSIN

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are or have been treated with GLYPRESSIN.

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 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.

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 GLYPRESSIN.

Like all medicines, GLYPRESSIN 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 GLYPRESSIN

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

GLYPRESSIN is given as intravenous injection:

Solution for Injection

- this is a clear, colourless solution containing 8.5mL of GLYPRESSIN solution (in an ampoule)
- available in a box containing 5 ampoules of GLYPRESSIN solution.

Ingredients

Active ingredient:

The active ingredient in GLYPRESSIN preparations is terlipressin.

Each ampoule of GLYPRESSIN Solution for Injection contains 0.85 mg terlipressin (equivalent to 1 mg of terlipressin acetate) in 8.5 mL solution.

Other ingredients:

Sodium chloride, Acetic acid, Sodium acetate trihydrate, Water for Injections

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

GLYPRESSIN is supplied in Australia by:

Ferring Pharmaceuticals Pty Ltd

ABN No. 87003 037 170

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20 Bridge Street

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Toll free: 1800 337 746

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Australian Register

Number(s):

GLYPRESSIN Solution for

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AUST R 177708

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