

PACKAGE LEAFLET: INFORMATION FOR THE USER

Glypressin® Injection

Terlipressin acetate



Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What GLYPRESSIN Injection is and what it is used for
2. Before you use GLYPRESSIN Injection
3. How GLYPRESSIN Injection is administered
4. Possible side effects
5. How to store GLYPRESSIN Injection
6. Contents of the pack and other information

1. WHAT GLYPRESSIN INJECTION IS AND WHAT IT IS USED FOR

Glypressin Injection consists of a powder and solvent for solution for injection. The white, freeze-dried powder contains terlipressin acetate.

Glypressin Injection is used in the treatment of bleeding oesophageal varices. Bleeding oesophageal varices are enlarged blood vessels that form in the stomach or oesophagus as a complication of liver disease. They may burst and bleed and this is a serious and life-threatening condition.

When injected into the bloodstream, the active ingredient, terlipressin acetate is broken down to release a substance called lysine vasopressin. This acts on the walls of the blood vessels, causing them to narrow and restrict the blood flow to the affected veins so that bleeding is reduced.

2. BEFORE YOU USE GLYPRESSIN INJECTION

Glypressin Injection should not be used:

- if you are pregnant
- if you are allergic to terlipressin acetate or any of the other ingredients of Glypressin listed in section 6.

Please consult your doctor before Glypressin Injection is administered to you:

- if you have hypertension (high blood pressure)
- if you have a heart condition (such as an irregular heart beat)
- if you have heart disease e.g. coronary insufficiency (a condition in which the arteries of the art become hardened, narrow or blocked leading to an insufficient blood supply to the heart muscle)
- if you have atherosclerosis (a disease of the arteries in which fatty plaques develop on the inner lining of the arteries, preventing blood from flowing normally)
- if you have a septic shock, a serious condition that occurs when a major infection leads to low blood pressure and low blood flow.

If any of the above apply to you (or you are not sure) talk to your doctor or nurse before you are given Glypressin.

Taking with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

Drugs that can trigger irregular beating of the heart (arrhythmia) such as the following:

- anti-arrhythmic drugs known as Class IA (quinidine, procainamide, disopyramide) and Class III (amiodarone, sotalol, ibutilide, dofetilide)
- erythromycin (an antibiotic)
- antihistamines (mainly used to treat allergies but also found in certain cough and cold remedies)
- tricyclic antidepressants used to treat depression
- medicines that may alter the level of salt or electrolytes in your blood, particularly diuretics (water tablets used to treat high blood pressure and heart failure).

Pregnancy and breast-feeding

You must not be given Glypressin if you are pregnant or breast-feeding. It is not known if Glypressin passes into the mother's milk.

Ask your doctor, nurse or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

3. HOW GLYPRESSIN INJECTION IS ADMINISTERED

The doctor will administer the appropriate dose by injection into a vein.

The usual dose of Glypressin Injection in acute bleeding from oesophageal varices is 2mg followed by 1 or 2 mg every 4 to 6 hours until bleeding is controlled, up to a maximum of 48 hours. During treatment, your blood pressure, serum sodium and potassium and fluid balance will normally be monitored constantly.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Glypressin can cause side effects, although not everybody gets them

Commonly reported side effects (affect less than 1 in 10 people):

- Headache
- Raised blood pressure, very slow heart rate
- Stomach pains, cramps or diarrhoea
- Skin becoming white which usually goes away after a short time (transient blanching)

Uncommon (may affect up to 1 in 100 people):

- Heart failure, rare form of rapid heart beat (Torsade de pointes).
- Skin damage
- Uterine cramps
- Decreased blood flow to the uterus
- Low sodium in the blood
- Irregular or rapid heartbeat, palpitations, chest pain, heart attack
- Fluid in the lungs, severe breathing problems
- Bluish discoloration of the skin and mucous membranes
- Hot flush
- Feeling or being sick
- Skin damage at the injection site
- Muscle weakness and twitching (symptoms of hyponatraemia)
- Frequent forceful bowel movements, blood in stools (symptoms of intestinal ischaemia)

Rare cases (may affect up to 1 in 1,000 people):

- Difficulty breathing

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE GLYPRESSIN INJECTION

Keep Glypressin Injection out of the reach and sight of children.

Do not store above 25°C. Keep container in the outer carton.

Do not use after the expiry date marked on the packaging.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

Your medicine is called Glypressin Injection. Each carton has:

- one vial of freeze-dried powder containing 1mg of the active ingredient, terlipressin acetate, and mannitol. Hydrochloric acid is added to adjust the acidity
- one ampoule of liquid (solvent) containing a 5ml solution of sodium chloride in water for injection to dissolve the powder before injection. Hydrochloric acid is added to adjust the acidity to make it suitable for injection.

Marketing Authorisation Holder:

Ferring Pharmaceuticals Ltd.

Drayton Hall, Church Road, West Drayton, UB77PS, UK.

Manufacturer

Ferring GmbH

Wittland 11, D-24109 Kiel, Germany

Glypressin Injection PL 03194/0018

This leaflet was last revised in December 2020.

Date: 03 Sep 2021

Title	Leaflet GLYPRESSIN powd and solv for sol for inj vial 5x 1mg		
Ferring Item N°	5009001451	Perigord N°	621901
TPM Item N°	N/A	Approving Country(ies)	GB
Proof N°	01	Dimensions	130x300 mm
F-MS N°	3015	Perforation pre-cut	<input type="checkbox"/>
Barcode N°	5009001451		
Colours	P Pro Black.		