GLYPRESSIN® PATIENT INFORMATION LEAFLET

Scheduling Status: S4

Proprietary name, strength and pharmaceutical form:

GLYPRESSIN® 0,1 mg/ml solution for injection**.**

Please read this leaflet carefully before receiving GLYPRESSIN®.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- GLYPRESSIN® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT GLYPRESSIN® CONTAINS

GLYPRESSIN® solution for injection contains the active ingredient terlipressin acetate. Each ampoule contains 1 mg of terlipressin acetate (0,85 mg terlipressin free base) in 8,5 ml solution for injection.

The inactive ingredients are sodium chloride, acetic acid, sodium acetate and water for injection. One ampoule contains 1,33 mmol (or 30,7 mg) sodium.

2. WHAT GLYPRESSIN® IS USED FOR

When GLYPRESSIN® is injected into the bloodstream, the active ingredient, terlipressin acetate, is broken down to release a substance called lysine vasopressin. This substance acts on the walls of your blood vessels, causing them to narrow and decrease the blood flow to your affected veins. This helps stop or slow the bleeding.

GLYPRESSIN® is used to treat bleeding oesophageal varices.

3. BEFORE YOU RECEIVE GLYPRESSIN®

Do not use GLYPRESSIN®:

- If you are allergic (hypersensitive) to terlipressin acetate or any of the other ingredients in GLYPRESSIN®.
- If you are pregnant.

Special care should be taken with GLYPRESSIN®:

Please check with your doctor before GLYPRESSIN® is given to you if:

- You have high blood pressure (hypertension).
- You have heart disease
- You have septic shock

Caution is required in elderly patients as experience is limited in these age groups.

GLYPRESSIN® should not be used in children.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking GLYPRESSIN®.

You must not be given GLYPRESSIN® if you are pregnant.

You must not be given GLYPRESSIN® if you are breastfeeding. It is not known if GLYPRESSIN® passes into the mother's milk.

Driving and using machinery:

Not applicable. GLYPRESSIN® is a medicine that is only used in hospitals.

Important information about some of the ingredients of GLYPRESSIN®:

GLYPRESSIN® contains 1,33 mmol (or 30,7 mg) of sodium per ampoule. Please tell your doctor if you are on a sodium controlled diet.

Taking other medicines with GLYPRESSIN®:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

It is most important to tell your doctor if you are taking any kind of heart medication (e.g. propranolol or other beta-blockers) as their effect could be increased if used at the same time as GLYPRESSIN®.

4. HOW GLYPRESSIN® IS USED

GLYPRESSIN® is used in hospitals and will be given to you by a doctor or a nurse.

GLYPRESSIN® will be given to you as an injection into a vein (directly into the bloodstream).

During treatment, your blood pressure, serum sodium and potassium and fluid balance will be monitored closely.

If you receive more GLYPRESSIN® than you should:

The recommended dose (2 mg/4 hours) should not be exceeded as the risk of severe circulatory adverse effects is dose-dependent.

Increase in blood pressure in patients who are diagnosed with high blood pressure can be controlled with 150 microgram clonidine, intravenous

Bradycardia (very slow heart rate) may be treated with atropine.

Treatment is symptomatic and supportive.

5. POSSIBLE SIDE EFFECTS

GLYPRESSIN® can have side effects.

Not all side effects reported for GLYPRESSIN® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Frequently reported side effects include:

- Headache
- Bradycardia (very slow heart rate)

- Increased blood pressure
- Transient stomach pain
- Peripheral constriction of blood vessels (inadequate blood flow to the tissue) resulting in paleness.
- Transient diarrhoea

Less frequently reported side effects include:

- Low blood sodium if fluid is not monitored.
- Irregular heart beat
- Increased pulse rate
- Chest pain
- Myocardial infarction (heart attack)
- Pulmonary oedema (fluid accumulation in your lungs)
- Inadequate blood flow to the guts
- Peripheral cyanosis (bluish discolouration of the skin caused by lack of oxygen)
- Hot flushes
- Respiratory distress and respiratory failure (difficulties in breathing)
- Transient nausea
- Transient vomiting
- Skin necrosis (tissue damage) at the injection site

Other side effects that have been reported:

- Dyspnoea (difficulties in breathing)
- Heart failure. Symptoms include: shortness of breath, tiredness and swollen ankles
- Torsade de pointes (acute cardiac event)
- Skin necrosis (tissue damage)
- Uterine constriction (constriction of the womb)
- Decreased blood flow in the womb

Not all side effects reported for GLYPRESSIN® are included in this leaflet. If you notice any side-effects

not mentioned in this leaflet, or if your general health worsens while taking, GLYPRESSIN® please tell your doctor, pharmacist or other health care professional

6. STORING AND DISPOSING OF GLYPRESSIN®

Store in a refrigerator at 2 to 8 °C.

Keep the ampoules in the outer carton in order to protect from light.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

For single use only

Do not use GLYPRESSIN® after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Discard any unused portion. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF GLYPRESSIN®

8, 5 ml GLYPRESSIN® Solution for Injection is filled into clear, type I glass ampoules. Each pack contains 5 ampoules in a plastic tray.

8. IDENTIFICATION OF GLYPRESSIN®

Clear, colourless solution for injection.

9. REGISTRATION NUMBER

43/21.13/0829

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Ferring (Pty) Ltd.

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11. DATE OF PUBLICATION

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