Terlipressin

Solution for Injection

MADE IN GERMANY

Terlipressin EVER Pharma was developed to offer a more convenient and safer to handle product than the originator Glypressin®. Available as a ready to use solution in a vial, there is no need to either reconstitute the product with solvent or break open ampoules.

Both initial and maintenance dose ranges are conveniently and economically covered by providing a 10 ml vial in addition to the current 5 ml vial.

Terlipressin EVER Pharma is indicated for the treatment of bleeding oesophageal varices and Hepato-renal syndrome type I.

- **Ready to use product** - for immediate use without reconstitution
- **Available in vials** - safer and more convenient than ampoules
- **5 ml and new 10 ml presentation** covering initial and maintenance dose ranges
- **Additional indication** - for Hepatorenal syndrome type I

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Indications	Treatment of bleeding oesophageal varices, emergency treatment of type 1 hepatorenal syndrome, as defined by IAC (International Ascites Club) criteria
Active Ingredient	Terlipressin acetate
Excipients	Sodium chloride , Acetic acid, Sodium hydroxide (for pH-adjustment), Hydrochloric acid (for pH-adjustment), Water for injections
Presentations	■ **1 mg/5 ml** solution for injection ■ **2 mg/10 ml** solution for injection
Strengths	■ **5 ml of injection solution** contains 1 mg terlipressin acetate corresponding to 0.85 mg terlipressin ■ **10 ml of injection solution** contains 2 mg terlipressin acetate corresponding to 1.7 mg terlipressin
Stability	■ **Unopened:** 24 months, Store in a refrigerator (2°C to 8°C). Do not freeze ■ **After 1st Opening:** Use Immediately
Primary Packaging	Type I Colourless glass vial with bromobutyl rubber stopper and sealed with aluminium flip-off cap
Pack sizes	1 or 5 vials per pack

Terlipressin acetate EVER Pharma 0.2 mg/ml solution for injection. Composition: Each 1 ml contains 0.2 mg Terlipressin acetate corresponding to 0.17 mg Terlipressin. List of excipients: Sodium chloride, Acetic acid, Sodium hydroxide (for pH-adjustment), Hydrochloric acid (for pH-adjustment), Water for injections. Therapeutic indications: Treatment of bleeding oesophageal varices. Emergency treatment of type 1 hepatorenal syndrome, as defined by IAC (International Ascites Club) criteria. Contraindications: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1., Pregnancy. Side effects: common: headache, ventricular and supra-ventricular arrhythmia, bradycardia, signs of ischaemia in the ECG, hypertension, hypotension, peripheral ischaemia, peripheral vasoconstriction, facial pallor, transient abdominal cramps, transient diarrhea, paleness, abdominal cramps (in women), uncommon: hyponatraemia, triggering of a convulsive disorder, angina pectoris, acute hypertension rise, in particular in patients already suffering from hypertension (generally, it decreases spontaneously), atrial fibrillation, ventricular extrasystoles, tachycardia, chest pain, myocardial infarction, fluid overload with pulmonary oedema, intestinal ischaemia, peripheral cyanosis, hot flushes, pain in the chest, bronchospasm, respiratory distress, respiratory failure, transient nausea, transient vomiting, lymphangitis, rare: hyperglycaemia, stroke, myocardial ischemia, dyspnoea, local cutaneous necrosis. More information about pharmaceutical form, posology and method of administration, special warnings and precautions for use, interaction with other medicinal products and other forms of interaction, fertility, pregnancy and lactation, effects on ability to drive and use machines, undesirable effects, overdose, pharmacodynamics properties, pharmacokinetic properties, preclinical safety data, incompatibilities, shelf life, special precautions for storage, nature and contents of the container and special precautions for disposal is available in the summary of product characteristics. Only available on prescription. Last update: June 2016, Marketing Authorisation Holder: EVER Valinject GmbH, Oberburgau 3, A-4866 Unterach

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