Terlipressin

Solution for Injection

MADE IN GERMANY

1 mg
5 ml

Terlipressin EVER Pharma is a ready-to-use solution in a vial. There is no need to reconstitute or break open ampoules.

Indicated for the treatment of bleeding oesophageal varices and hepatorenal syndrome type 1.

- **Ready-to-use** – no reconstitution from powder required
- **Supplied in vials** – safer and more convenient than ampoules
- **Additional indication** – for Hepatorenal syndrome type I

www.everpharma.com

EVER PHARMA

Terlipressin

Solution for Injection

MADE IN GERMANY

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
Strengths	Each 1 ml of solution contains 0.2 mg terlipressin acetate, equivalent to 0.17 mg terlipressin (a 5 ml vial contains 1 mg terlipressin acetate / 0.85 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 a rubber stopper, sealed with an aluminium crimp cap, covered with a plastic 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

EVER PHARMA