For the use of a registered medical practitioner or a hospital or a laboratory only.

Rx Terlipressin Injection 0.1mg/ml

TERLIFORT™

INJECTION

टरलीफोर्ट

Composition :

Each ml contains :

Terlipressin (As Terlipressin Acetate)	BP	0.1 mg
Water for Injections	IP	q.s.

Indications

1. To arrest bleeding at the time of surgery particularly of the abdominal and pelvic area.
2. To arrest bleeding in gastrointestinal and urogenital systems such as oesophageal varices, gastric and duodenal ulcerations, functional and similar types of metrorrhagia etc.
3. Hepatorenal syndrome.
4. Local application in gynaecological operations, such as cervix porta uteri.

Dosage and method of Administration

Bleeding Oesophageal Varices

Adults : Initial bolus dose 2 mg should be administered by an intravenous bolus Injection over one minute, followed by 1 mg-2mg every 4-6 hours for next 24-48 hours. For prevention of bleeding recurrence, continued medication shall be recommended until the bleeding has been controlled. The dose shall be administered through I.V. (as a rule bolus) injection or short-term infusion.

Children : 8 to 20 mcg/kg of body weight given at intervals of 4-8 hours.

Hepatorenal syndrome : 1-2 mg twice daily as I.V. bolus for 2-4 weeks. Dose may be adjusted if required.

Bleeding from the urogenital tract

The dosage will range 0.2-1.0 mg (200-1000 mcg) every 4-6 hours.

Juvenile Metrorrhagia

For juvenile metrorrhagia, doses of 5-20mcg/kg of body weight are recommended. The administration shall be intravenous.

Local application in gynaecological operations

Add saline to 0.4mg (400mcg) dose to obtain 10ml and apply intracervically or paracervically. The effects of such preparation can be seen after approx. 5-10 minutes. If necessary, increase or repeat the dose.

Overdose

Dose of above 2mg/4 hours(2000 mcg/4hours) increase the risk of serious adverse effects on systemic circulation. Therefore, maximum prescribed dosage regimen should not be exceeded. In case of hypertension or bradycardia, the respective therapeutic measure should be taken.

Contraindications

Terlifort is contraindicated for the first three months of pregnancy, unless the indication is non-vital, pregancy toxicosis, epilepsy. The benefits against risk in the following months of pregnancy always should be considered.

NOTE :

Special care and precautions should be taken when administering to elderly, patients with ischemia, serious hypertension, cardiac arrhytmia or asthma bronchiale.

Warnings and precautions

Drug interactions

Both oxytocin and methylergometrine increase the vascconstrictive and uterotonic effects. Terlipressin enhances the hypotensive effect of non-selective blockers in the portal vein. Parallel medications with substances lowering heart rate can result in serious bradycardia.

General

For administration of Terlifort in doses higher than 0.8mg = 800mcg or more to patients with hypertension, heart insufficiency and senior patients it is recommended to tightly monitor the blood pressure, heart rate and hemodyamic balance .Terlifort is not meant as a replacement of blood substitution in patients with blood volume deficit.

Pregnancy

Terlipressin causes rise in myometrial activity and decrease in uteral blood flow. Reproduction studies in rabbits and rats with higher doses showed increased abortion rate or embryo deaths. In infants, lower birth weight as well as increased anomaly rate has been found, Terlipressin is contraindicated in pregnancy.

Lactation

Terlipressin distrubution in breast milk is not available; however significant absorption of unchanged peptides in gastrointestinal system of child seems not to be probable, There is no definite data on Terlipressin use in lactating women.

Pediatric use

There is very limited clinical experience in children, caution to be exercised during use in this group of patients.

Geriatric use

There is very limited clinical experience in elderly, caution to be exercised during use in this group of patients.

Undesirable effects

The most frequent undesirable effects in course of administration are: skin pallor, hypertension, accelerated defaecation or abdominal colics, nausea, diarrhoea and bradycardia. Serious adverse effects are rare. Individual cases of heart attack, heart failure, dyspnoea and local necrosis at the site of injection were also reported.

Pharmacology

Terlipressin may be regarded as a circuating depot of lysine vasopressin. Following intravenous injection, three glycyl moieties are enzymatically cleaved from the N-teminus to release lysine vasopressin. Compared with lysine-vasopressin, the effect comes more slowly, however for much longer, Lysine-vasopressin is subject to usual biodegradation in liver, kidneys and other tissues. The intravenous pharmacological profile can be described using a two-compartment model. The excretion half-life is before administration.

Pharmacodynamics

Terlipressin has significant vasoconstrictive and anti-haemorrhagic effect. The most significant change is reduced blood flow in splanchnic area with following reduction of hepatic blood flow and portal blood pressure. Pharmacodymic studies have shown that like other similar peptides, Terlipressin causes intrarteriolar, intravenous and intravenular constrictions primarily in splanchnic area as well as constriction of oesophagel unstripped muscles and increase in tones and intestinal peristaltic activity. In addition to its vasopressor effects, Terlipressin stimulates myometrial activity, even in nonpregnant uterus. The results of animal and human studies support the hypothesis of most intense Terlipressin activity in splanchnic area and skin. The anti-shock effect of Terlipressin has been confirmed not only for haemorrhagic but also for endotoxic and histaminic shocks. There are no clinical manifestations of the antiduretic effect of Terlipressin.

Pharmacokinetics

Terlipressin as such is inactive in relation to comparement model. The excretion half-life is about 51 to 66 minutes, metabolic clearance about 9 ml/kg x min and distribution volume about 0.6 to 0.9 l/kg. Estimated Lysine vasopressin concentration can be found in plasma 30 minutes after administration of Terlipressin with peak values after 60-120 minutes.

Shelf-life

24 months

Storage and handling instructions

Store at a temperature between 2°C to 8°C. Protect from light. Do not Freeze

Packing Information

1 Mono Carton containing 1 Ampoule of 10 ml.

SUNFORT® INDIA

Manufactured in India for :
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