Atosiban

MADE IN GERMANY

Solution for Injection, Concentrate for Solution for Infusion

Available as a convenient ready to use fixed dose (6.75 mg/0.9 ml bolus injection), and as a concentrate for dilution (high dose/low dose infusions).

Atosiban is an inhibitor of the hormones oxytocin and vasopressin. It is administered intravenously as a labour repressant (tocolytic) to halt premature labour.

- **Ready to use product -** either for immediate use or dilution for infusion
- **No reconstitution from powder required**
- **Available in vials -** safer and more convenient than ampoules
- **Available in 3 presentations including new 10 ml vial -** conveniently covering loading, and high dose/low dose infusion administration stages

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Indications

Is indicated to delay imminent pre-term birth in pregnant adult women with: regular uterine contractions of at least 30 seconds duration at a rate of ≥ 4 per 30 minutes, a cervical dilation of 1 to 3 cm (0-3 for nulliparas) and effacement of ≥50%, a gestational age from 24 until 33 completed weeks, a normal foetal heart rate

Active Ingredient

Atosiban acetate

Excipients

Mannitol, Hydrochloric acid 1M (for pH adjustment), Sodium hydroxide (for pH adjustment), Water for injections

Presentations

- **6.75 mg/0.9 ml** solution for injection
- **37.5 mg/5 ml** concentrate for solution for infusion
- **75 mg/10 ml** concentrate for solution for infusion

Strength

Each 1 ml of concentrate contains 7.5 mg atosiban.

Stability

- **Unopened:** 24 months. Store in a refrigerator (2°C to 8°C)
  Store in the original package in order to protect from light
- **After 1st Opening:** Once the vial has been opened, the product must be used immediately
- **Solution for Infusion:** Chemical and physical in-use stability has been demonstrated for 48 hours at room temperature with and without light protection and refrigerated conditions. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C, unless dilution has taken place in controlled and validated aseptic conditions

Primary Packaging

Type I colourless glass vial

Pack sizes

1 vial per pack.

Atosiban EVER Pharma 6.75 mg/0.9 ml solution for injection, Atosiban EVER Pharma 37.5 mg/5 ml concentrate for solution for infusion; Atosiban EVER Pharma 75 mg/10 ml concentrate for solution for infusion. Composition: Each vial of 0.9 ml solution contains 6.75 mg Atosiban (as acetate). Each vial of 5 ml concentrate contains 37.5 mg Atosiban (as acetate). Each vial of 10 ml concentrate contains 75 mg Atosiban (as acetate). Each ml of concentrate contains 7.5 mg Atosiban. After dilution, the concentration of Atosiban is 0.75 mg/ml. List of excipients: mannitol, hydrochloric acid 1M (for pH adjustment), sodium hydroxide (for pH adjustment), water for injections. Therapeutic indications: Atosiban is indicated to delay imminent pre-term birth in pregnant adult women with: regular uterine contractions of at least 30 seconds duration at a rate of ≥ 4 per 30 minutes; a cervical dilation of 1 to 3 cm (0-3 for nulliparas) and effacement of ≥ 50%; a gestational age from 24 until 33 completed weeks; a normal foetal heart rate. For intravenous use only. Contraindications: Atosiban must not be used in the following conditions: gestational age below 24 or over 33 completed weeks, premature rupture of the membranes >30 weeks of gestation, abnormal foetal heart rate, antepartum uterine haemorrhage requiring immediate delivery, eclampsia and severe pre-eclampsia requiring delivery, intrauterine foetal death, suspected intrauterine infection, placenta praevia, abruptio placenta, any other conditions of the mother or foetus, in which continuation of pregnancy is hazardous, hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1. Side effects: very common: nausea; common: hyperglycaemia, headache, dizziness, tachycardia, hypotension, hot flush, vomiting, injection site reaction, uncommon: insomnia, pruritis, rash, pyrexia, rare: allergic reaction, uterine haemorrhage, uterine atony. 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: September 2016, Marketing Authorisation Holder: EVER Valinject GmbH, Oberburgau 3, A-4866 Unterach

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