

Atosiban

MADE IN GERMANY

Solution for Injection / Concentrate for Solution for Infusion



6.75 mg
0.9 ml

37.5 mg
5 ml

75 mg
10 ml

Atosiban EVER Pharma is available as a ready-to-use fixed-dose bolus injection (6.75 mg/0.9 ml) and as a concentrate for dilution for low- (37.5 mg/5 ml) and high-dose (75 mg/10 ml) infusions.

Indicated to delay imminent pre-term birth in pregnant adult women.

- **Ready-to-use product** – for immediate use or dilution for infusion
- **Available in three presentations including a 10 ml vial** – covering loading and high-/low-dose infusion stages



www.everpharma.com



Solution for Injection / Concentrate for Solution for Infusion

Indications	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 $\geq 50\%$, a gestational age from 24 until 33 completed weeks, a normal foetal heart rate.
Active Ingredient	Atosiban acetate
Excipients	Mannitol, Hydrochloric acid 1 M (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 vial of 0.9 ml solution contains 6.75 mg atosiban (as acetate). Each 1 ml of concentrate contains 7.5 mg atosiban (as acetate).
Stability	■ Unopened: 24 months. Store in a refrigerator (2°C to 8°C). Store in the original package to protect from light. ■ After 1st Opening: Use 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 under refrigerated conditions. From a microbiological point of view the product should be used immediately; if not, in-use storage times and conditions prior to use are the responsibility of the user and would normally not exceed 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 sealed with a rubber stopper, sealed with an aluminium crimp cap, covered with a plastic flip-off cap.
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 $\geq 50\%$; 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