

Oxytocin

Solution for Injection

MADE IN GERMANY



Oxytocin EVER Pharma is indicated for the induction of labour for medical reasons; stimulation of labour in hypotonic uterine inertia; during caesarean section, following delivery of the child; prevention and treatment of postpartum uterine atony and haemorrhage. Early stages of pregnancy as a adjunctive therapy for the management of incomplete, inevitable, or missed abortion.

- **Provided in ampoules** in 2 strengths, Oxytocin 10 IU/ml and 5 IU/ml
- **Shelf life 3 years** refrigerated (2°C to 8°C). May be stored below 25°C for 6 months, but then discarded.
- **Supplied in boxes** of 5, 10, 50 and 100 ampoules



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 **EVER
PHARMA**

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| Indications | Induction of labour for medical reasons; stimulation of labour in hypotonic uterine inertia; during caesarean section, following delivery of the child; prevention and treatment of postpartum uterine atony and haemorrhage. Early stages of pregnancy as a adjunctive therapy for the management of incomplete, inevitable, or missed abortion. |
| Active Ingredient | Oxytocin |
| Excipients | Sodium chloride, Sodium acetate tri-hydrate, Glacial acetic acid, Water for injections |
| Presentations | <ul style="list-style-type: none">■ 5 IU/1 ml solution for injection■ 10 IU/1 ml solution for injection |
| Strengths | <ul style="list-style-type: none">■ 5 IU: Each ml of solution contains 8.5 micrograms of oxytocin EP in solution. Each 1 ml ampoule also contains 2.9 mg (0.13 mmol) of sodium.■ 10 IU: Each ml of solution contains to 17 micrograms of oxytocin EP in solution. Each 1 ml ampoule also contains 2.9 mg (0.13 mmol) of sodium. |
| Stability | <ul style="list-style-type: none">■ Unopened: 36 months. Store in a refrigerator (2°C to 8°C). May be stored below 25°C for 6 months, but then discarded.■ After 1st Opening: Not applicable■ Solution for Injection: Use immediately |
| Primary Packaging | Type I colourless glass 1ml ampoules |
| Pack sizes | 5, 10, 50 or 100 ampoules per pack. |

Oxytocin EVER Pharma 5 IU/ml Solution for Injection, Oxytocin EVER Pharma 10 IU/ml Solution for Injection. Composition: Each 1 ml of solution contains 5 IU oxytocin, equivalent to 8.5 micrograms of oxytocin EP in solution. Each 1 ml of solution contains 10 IU oxytocin, equivalent to 17 micrograms of oxytocin EP in solution. Each 1 ml ampoule also contains 2.9 mg (0.13 mmol) of sodium. List of excipients: sodium chloride, sodium acetate tri-hydrate, glacial acetic acid, water for injections. Therapeutic indications: Induction of labour for medical reasons; stimulation of labour in hypotonic uterine inertia; during caesarean section, following delivery of the child; prevention and treatment of postpartum uterine atony and haemorrhage. Early stages of pregnancy as a adjunctive therapy for the management of incomplete, inevitable, or missed abortion. For intravenous use only. Contraindications: Hypersensitivity to the active substance or to any of the excipients, Dystocia, Fragility or overdistension of the uterus, Hypertonic uterine contractions or foetal distress, when delivery is not imminent, Pre-eclamptic toxemia and severe cardiovascular disorders, Predisposition to amniotic fluid embolism (foetal death in utero, retroplacental hematoma), Placenta praevia. Side effects: exceptionally: skin rashes, anaphylactoid reaction or anaphylactic shock, common: tachycardia, bradycardia, rarely: arrhythmia, nausea, vomiting, very rarely: headache, seizures. 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 2018, Marketing Authorisation Holder: EVER Neuro Pharma GmbH, Oberburgau 3, A-4866 Unterach