

# Oxytocin

Solution for Injection



**Oxytocin is a hormone released by the pituitary gland, which stimulates contraction of the muscles of the uterus (womb).**

Oxytocin EVER Pharma is a generic version of Syntocinon® (Novartis) and 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

# Oxytocin

## Solution for Injection



<b>Active Ingredient</b>	Oxytocin
<b>Excipients</b>	Sodium chloride, Sodium acetate tri-hydrate, Glacial acetic acid, Water for injections
<b>Primary Packaging</b>	Colourless glass (Type I) 1 ml ampoules
<b>Presentations</b>	5 IU/ml ampoule, 10 IU/ml ampoule
<b>Active Strengths</b>	5 IU oxytocin: Each ml of solution contains 8.5 micrograms of oxytocin EP in solution. Each 1ml ampoule also contains 2.9mg (0.13 mmol) of sodium 10 IU oxytocin: Each ml of solution contains 17 micrograms of oxytocin EP in solution. Each 1ml ampoule also contains 2.9mg (0.13 mmol) of sodium
<b>Pack sizes</b>	Boxes containing 5, 10, 50 and 100 ampoules
<b>Indications</b>	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.
<b>Stability</b> Unopened	3 years. Store in a refrigerator (2°C to 8°C) May be stored below 25°C for 6 months, but then discarded
<b>After 1st Opening</b>	Not applicable
<b>Solution for Infusion</b>	Use immediately

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 haematoma), 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