

**Description**

Oxytocin (**Ocin®**) is a synthetic nonapeptide identical with Oxytocin, a hormone released by the posterior lobe of the pituitary. It exerts a stimulatory effect on the smooth musculature of the uterus, particularly towards the end of pregnancy, during labour, after delivery, and in the puerperium, i.e., at times when the number of specific oxytocin receptors in the myometrium is increased.

**Mode of action**

Oxytocin (**Ocin®**) causes contraction of the uterus, the effect increasing with the duration of pregnancy due to proliferation of oxytocin receptors. Small doses increase the tone and amplitude of the uterine contractions. It also stimulates the smooth muscle associated with the secretory epithelium of the lactating breast causing the ejection of milk but having no direct effect on milk secretion. It has a weak antidiuretic action.

**Pharmacokinetics**

The plasma half-life of oxytocin (**Ocin®**) is of the order of five minutes, hence the need for continuous IV infusion. Elimination is via the liver, kidney, functional mammary gland and oxytocinase.

**Composition**

**Ocin® Injection:** Each ml ampoule contains Oxytocin BP 5 IU.

**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 an adjunctive therapy for the management of incomplete, inevitable, or missed abortion.

**Dosage & administration**

*Induction or enhancement of labour:* Oxytocin should be administered as an intravenous drip infusion or, preferably, by means of a variable-speed infusion pump. For drip infusion it is recommended that 5 IU of oxytocin be added to 500 ml of a physiological electrolyte solution. For patients in whom infusion of sodium chloride must be avoided, 5% dextrose solution may be used as the diluent. The initial infusion rate should be set at 1 to 4 mU/min (2 to 8 drops/min) which may be gradually increased at intervals not shorter than 20 min, until a contraction pattern similar to that of normal labour is established. In pregnancy near term this can often be achieved with an infusion of less than 10 mU/min (20 drops/min), and the recommended maximum rate is 20 mU/min (40 drops/min).

If in women who are at term or near term, regular contractions are not established after the infusion of a total amount of 5 IU, it is recommended that the attempt to induce labour be ceased; it may be repeated on the following day, starting again from a rate of 1 to 4 mU/min.

*Caesarean section:* 5 IU by slow IV injection immediately after delivery.

*Prevention of postpartum uterine haemorrhage:* The usual dose is 5 IU slowly IV after delivery of the placenta. In women given oxytocin for induction or enhancement of labour, the infusion should be continued at an increased rate during the third stage of labour and for the next few hours thereafter.

*Treatment of postpartum uterine haemorrhage:* 5 IU slowly IV, followed in severe cases by IV infusion of a solution containing 5 to 20 IU of oxytocin in 500 ml of a non-hydrating diluent, run at the rate necessary to control uterine atony.

*Incomplete, inevitable, or missed abortion:* 5 IU slowly IV, if necessary followed by IV infusion at a rate of 20 to 40 mU/min or higher.

**Contraindications**

Hypersensitivity to the drug. Hypertonic uterine contractions, mechanical obstruction to delivery, foetal distress. Any condition in which, for foetal or maternal reasons, spontaneous labour is inadvisable and/or

vaginal delivery is contraindicated. Oxytocin should not be used for prolonged periods in patients with oxytocin-resistant uterine inertia, severe pre-eclamptic toxemia or severe cardiovascular disorders.

**Side effects**

Administration at too high doses results in uterine overstimulation which may cause foetal distress, asphyxia and death, or may lead to hypertonicity, tetanic contractions, soft tissue damage or rupture of the uterus.

Water intoxication associated with maternal and neonatal hyponatraemia has been reported in cases where high doses of oxytocin together with large amounts of electrolyte-free fluid have been administered over a prolonged period of time. Rapid IV bolus injection of oxytocin at doses amounting to several IU may result in acute short-lasting hypotension accompanied with flushing and reflex tachycardia.

Oxytocin may occasionally cause nausea, vomiting, haemorrhage or cardiac arrhythmias. In a few cases, skin rashes and anaphylactoid reactions associated with dyspnea, hypotension, or shock have been reported.

**Use in pregnancy & lactation**

For pregnancy as per dosage and administration. Not applicable during lactation.

**Precautions**

The induction of labour by means of oxytocin should be attempted only when strictly indicated for medical reasons. Administration should only be under hospital conditions and qualified medical supervision. When given for induction and enhancement of labour, oxytocin must only be administered as an IV infusion and never by IV bolus injection. Careful monitoring of foetal heart rate and uterine motility (frequency, strength and duration of contractions) is essential, so that the dosage may be adjusted to individual response.

When oxytocin is given for induction or enhancement of labour, particular caution is required in the presence of borderline cephalopelvic disproportion, secondary uterine inertia, mild or moderate degrees of pregnancy-induced hypertension or cardiac disease, and in patients above 35 years of age or with a history of lower-uterine-segment caesarean section.

**Drug interactions**

Since it has been found that prostaglandins potentiate the effect of oxytocin, it is not recommended that these drugs are used together. Some inhalation anaesthetics, e.g., cyclopropane or halothane, may enhance the hypotensive effect of oxytocin and reduce its oxytocic action. When given during or after caudal block anaesthesia, oxytocin may potentiate the pressor effect of sympathomimetic vasoconstrictor agents.

**Overdosage**

The fatal dose of oxytocin has not been established. It is not absorbed from the intestine and is not likely to have toxic effects when ingested. When signs or symptoms of overdosage occur during continuous IV administration of oxytocin, the infusion must be discontinued at once and oxygen should be given to the mother. In cases of water intoxication it is essential to restrict fluid intake, promote diuresis, correct electrolyte imbalance, and control convulsions that may eventually occur, by judicious use of diazepam. In the case of coma, a free airway should be maintained with routine measures normally employed in the nursing of the unconscious patient.

**Storage**

Store in a cool (Below 25°C temperature) and dry place protected from light.

**Packaging**

**Ocin® Injection:** Each carton contains 5X5 ampoules in blister pack.