OVERDOSE : The fatal dose of Oxytocin has not been established. Oxytocin is subject to inactivation by proteolytic enzymes of the alimentary tract. Hence it is not absorbed from the intestine and is not likely to have toxic effects when ingested.
The symptoms and consequences of overdosage are those mentioned under "Undesirable effects". In addition, as a result of uterine overstimulation, placental abruption and/or amniotic fluid embolism have been reported.
Treatment: 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.
PHARMACOLOGICAL PROPERTIES :
Pharmacodynamic properties :
The active principle of Oxytocin 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.
When given by low-dose iv infusion, Oxytocin elicits rhythmic uterine contractions that are indistinguishable in frequency, force, and duration from those observed during spontaneous labour. At higher infusion dosages, or when given by single injection, the drug is capable of causing sustained uterine contractions.
Being synthetic, Oxytocin does not contain vasopressin, but even in its pure form oxytocin possesses some weak intrinsic vasopressin-like antidiuretic activity.
Another pharmacological effect observed with high doses of oxytocin, particularly when administered by rapid iv bolus injection, consists of a transient direct relaxing effect on vascular smooth muscle, resulting in brief hypotension, flushing and reflex tachycardia.
Pharmacokinetic properties :
The plasma half-life of oxytocin 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.
Preclinical safety data :
There are no pre-clinical data of relevance to the prescriber which are additional to those already included in other sections of the Summary of Product Characteristics.

Store between 2° to 8°C. Avoid freezing.

Keep out of reach of children.

PRESENTATION : 1ml Ampoule/10 x 1ml Ampoules/100 x 1ml Ampoules

Manufactured in India by:
Ciron Drugs
& Pharmaceuticals Pvt. Ltd.
N-118/119, M.I.D.C., Tarapur,
Boisar, Dist.Thane-401 506.
www.cironpharma.com

OXYTOCIN INJECTION BP

Composition :
Each ml contains:
Oxytocin BP 10 IU
CLINICAL PARTICULARS :
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.
POSOLOGY AND METHOD OF ADMINISTRATION:
Induction or enhancement of labour : Oxytocin should not be started for 6 hours following administration of vaginal prostaglandins. Oxytocin should be administered as an iv 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 500ml 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 (see "Special warnings and precautions for use"). To ensure even mixing, the bottle or bag must be turned upside down several times before use.
The initial infusion rate should be set at 1 to 4mU/min (2 to 8 drops/min). It 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 10mU/min (20 drops/min), and the recommended maximum rate is 20mU/min (40 drops/min). In the unusual event that higher rates are required, as may occur in the management of foetal death in utero or for induction of labour at an earlier stage of pregnancy, when the uterus is less sensitive to oxytocin, it is advisable to use a more concentrated Oxytocin solution, e.g., 10 IU in 500ml.
When using a motor-driven infusion pump which delivers smaller volumes than those given by drip infusion, the concentration suitable for infusion within the recommended dosage range must be calculated according to the specifications of the pump.
The frequency, strength, and duration of contractions as well as the foetal heart rate must be carefully monitored throughout the infusion. Once an adequate level of uterine activity is attained, aiming for 3 to 4 contractions every 10 minutes, the infusion rate can often be reduced. In the event of uterine hyperactivity and/or foetal distress, the infusion must be discontinued immediately.
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 4mU/min (see "Contra-indications").
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 500ml 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 40mU/min or higher.
Children: Not applicable.
Elderly: Not applicable.

Route of administration: Intravenous infusion or intravenous injection.
CONTRAINDICATIONS : Known hypersensitivity to oxytocin or to any of the excipients of Oxytocin. 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 contra-indicated: e.g., significant cephalopelvic disproportion; foetal malpresentation; placenta praevia and vasa praevia; placental abruption; cord presentation or prolapse; overdistension or impaired resistance of the uterus to rupture as in multiple pregnancy; polyhydramnios; grand multiparity and in the presence of a uterine scar resulting from major surgery including classical caesarean section.
Oxytocin should not be used for prolonged periods in patients with oxytocin-resistant uterine inertia, severe pre-eclamptic toxaemia or severe cardiovascular disorders.
SPECIAL WARNINGS AND PRECAUTIONS FOR USE : 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. Administration of oxytocin at excessive doses results in uterine overstimulation which may cause foetal distress, asphyxia and death, or may lead to hypertonicity, titanic contractions or rupture of the uterus. 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.
In rare circumstances, the pharmacological induction of labour using uterotonic agents increases the risk of post patum disseminated intravascular coagulation (DIC). The pharmacological induction itself and not a particular agent is linked to such risk. This risk is increased in particular if the woman has additional risk factors for DIC such as being 35 years of age or over, complications during pregnancy and gestational age more than 40 weeks. In these women, oxytocin or any other alternative drug should be used with care, and the practitioner should be alerted by signs of DIC.
In the case of foetal death in utero, and/or in the presence of meconium-stained amniotic fluid, tumultous labour must be avoided, as it may cause amniotic fluid embolism.
Because oxytocin possesses slight antidiuretic activity, its prolonged iv administration at high doses in conjunction with large volumes of fluid, as may be the case in the treatment of inevitable or missed abortion or in the management of postpartum haemorrhage, may cause water intoxication associated with hyponatraemia. To avoid this rare complication, the following precautions must be observed whenever high doses of oxytocin are administered over a long time: an electrolyte-containing diluent must be used (not dextrose); the volume of infused fluid should be kept low (by infusing oxytocin at a higher concentration than recommended for the induction or enhancement of labour at term); fluid intake by mouth must be restricted; a fluid balance chart should be kept, and serum electrolytes should be measured when electrolyte imbalance is suspected.
When Oxytocin is used for prevention or treatment of uterine haemorrhage, rapid iv injection should be avoided, as it may cause an acute short-lasting drop in blood pressure accompanied with flushing and reflex tachycardia.
INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION : Since it has been found that prostaglandins potentiate the effect of oxytocin, it is not recommended that these drugs are used together. If used in sequence, the patient's uterine activity should be carefully monitored.
Some inhalation anaesthetics, e.g., cyclopropane or halothane, may enhance the hypotensive effect of oxytocin and reduce its oxytocic action. Their concurrent use with oxytocin has also been reported to cause cardiac rhythm disturbances.
When given during or after caudal block anaesthesia, oxytocin may potentiate the pressor effect of sympathomimetic vasoconstrictor agents.
Pregnancy and lactation : Animal reproduction studies have not been conducted with oxytocin. Based on the wide experience with this drug and its chemical structure and pharmacological properties, it is not expected to present a risk of foetal abnormalities when used as indicated.
Oxytocin may be found in small quantities in mother's breast milk. However, oxytocin is not expected to cause harmful effects in the newborn because It passes into the alimentary tract where it undergoes rapid inactivation.
Effects on ability to drive and use machines : Oxytocin can induce labour, therefore caution should be exercised when driving or operating machines. Women with uterine contractions should not drive or use machines.
Undesirable effects : As there is a wide variation in uterine sensitivity, uterine spasm may be caused in some instances by what are normally considered to be low doses. When oxytocin is used by iv infusion for the induction or enhancement of labour, 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 (see "Special warnings and precautions for use"). Symptoms of water intoxication include:

1. Headache, anorexia, nausea, vomiting and abdominal pain.
2. Lethargy, drowsiness, unconsciousness and grand-mal type seizures.
3. Low blood electrolyte concentration.

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.
In rare circumstances the pharmacological induction of labour using uterotonic agents increases the risk of postpartum disseminated intravascular coagulation (see Special warnings and special precautions for use).
Oxytocin may occasionally cause nausea, vomiting, haemorrhageor cardiac arrhythmias. In a few cases, skin rashes and anaphylactoid reactions associated with dyspnoea, hypotension, or shock have been reported.

Immune System disorders	
Rare:	Anaphylactoid reaction associated with dyspnoea, hypotension or shock
Nervous system disorders	
Common:	Headache
Cardiac disorders	
Common:	Tachycardia, bradycardia
Uncommon:	Arrhythmia
Gastrointestinal disorders	
Common:	Nausea, vomiting
Skin and subcutaneous tissue disorders	
Rare:	Rash