

Abridged prescribing information

Partocin™

(Oxytocin Injection IP) Synthetic

DESCRIPTION

Partocin (Oxytocin Injection, IP) is a sterile, clear, colorless aqueous solution of synthetic oxytocin, for intravenous infusion or intramuscular injection. Partocin contains oxytocin which is a nonapeptide hormone released by posterior lobe of the pituitary.

COMPOSITION

Each ml contains 5 IU of Oxytocin IP, 0.5% Chlorobutol IP, Water for Injection IP qs.

CLINICAL PHARMACOLOGY

Uterine motility depends on the formation of the contractile protein actomyosin under the influence of the Ca²⁺-dependent phosphorylating enzyme myosin light-chain kinase. Oxytocin promotes contractions by increasing the intracellular Ca²⁺. Oxytocin has specific receptors in the myometrium & the receptor concentration increases greatly during pregnancy, reaching a maximum in early labor at term. Oxytocin is distributed throughout the extracellular fluid. Small amounts of the drug probably reach the fetal circulation. Oxytocin has a plasma half-life of about 1 to 6 minutes, which is decreased in late pregnancy & during lactation. Following intravenous administration of oxytocin, uterine response occurs almost immediately & subsides within 1 hour. Following intramuscular injection of the drug, uterine response occurs within 3 to 5 minutes & persists for 2 to 3 hours. Its rapid removal from plasma is accomplished largely by the kidney & the liver. Only small amounts are excreted in urine unchanged.

INDICATIONS & USAGE

- Antepartum:** Partocin is indicated for the initiation or augmentation of uterine contractions, where this is desirable & considered suitable for reasons of fetal or maternal concern, in order to achieve vaginal delivery.
- Postpartum:** Partocin is indicated for uterine contractions during the third stage of labor to prevent & treat postpartum uterine atony & hemorrhage. Treatment of puerperal bleeding, subinvolution of the uterus, & lochiometra.
- Cesarean delivery:** During cesarean section following the delivery of the child.

CONTRAINDICATIONS

Antepartum use of Partocin is contraindicated where there is significant cephalopelvic disproportion, in unfavorable fetal positions or presentations, such as transverse lies, which are undeliverable without conversion prior to delivery, in obstetrical emergencies where the benefit-to-risk ratio for either the fetus or the mother favors surgical intervention, in fetal distress where delivery is not imminent, where adequate uterine activity fails to achieve satisfactory progress, where the uterus is already hyperactive or hypertonic, in cases where vaginal delivery is contraindicated, such as invasive cervical carcinoma, active herpes genitalis, total placenta previa, vasa previa, placenta abruptio and cord presentation or prolapse of the cord, overdistension or impaired resistance of the uterus to rupture as in multiple pregnancy, polyhydramnios, grand multiparity, & in the presence of uterine scar resulting from major surgery including classical cesarean section, in patients with hypersensitivity to the drug

WARNINGS

Partocin, when given for induction of labor or augmentation of uterine activity, should be administered only by the intravenous route & with adequate medical supervision in a hospital.

PRECAUTIONS

Induction of labor with oxytocin should be attempted only when strictly indicated for medical reasons rather than for convenience. Overstimulation of the uterus by improper administration can be hazardous to both mother & fetus. Except in unusual circumstances, oxytocin should not be administered in the following conditions; fetal distress, hydramnios, partial placenta previa, prematurity, borderline cephalopelvic disproportion, and any condition in which there is a predisposition for uterine rupture, such as previous major surgery on the cervix or uterus including cesarean section, overdistension of the uterus, grand multiparity, or past history of uterine sepsis or of traumatic delivery. Maternal deaths due to hypertensive episodes, subarachnoid hemorrhage, rupture of the uterus, and fetal deaths due to various causes have been reported associated with the use of parenteral oxytocic drugs for induction of labor or for augmentation in the first & second stages of labor. Oxytocin has been shown to have an intrinsic antidiuretic effect, acting to increase water reabsorption from the glomerular filtrate. Consideration should, therefore, be given to the possibility of water intoxication, particularly when oxytocin is administered continuously by infusion & the patient is receiving fluids by mouth.

ADVERSE REACTIONS: Adverse reactions such as anaphylactic reaction, postpartum hemorrhage, cardiac arrhythmia, fatal afibrinogenemia, nausea, vomiting, premature ventricular contractions, pelvic hematoma, subarachnoid hemorrhage, hypertensive episodes, rupture of the uterus have been reported in the mother. Excessive dosage or hypersensitivity to the drug may result in uterine hypertonicity, spasm, tetanic contraction, or rupture of the uterus. Severe water intoxication with convulsions & coma has occurred, associated with a slow oxytocin infusion over a 24-hour period. Maternal death due to oxytocin-induced water intoxication has been reported.

The following adverse reactions has been reported in the fetus or neonate:

Due to induced uterine motility: Bradycardia, premature ventricular contractions & other arrhythmias, permanent CNS or brain damage, fetal death.

Due to use of oxytocin in the mother: Low APGAR scores at five minutes, neonatal jaundice, neonatal retinal hemorrhage, neonatal seizures have been reported with the use of Partocin.

OVERDOSAGE

Hyperstimulation with hypertonic or tetanic contractions can lead to tumultuous labor, uterine rupture, cervical & vaginal lacerations, postpartum hemorrhage, uteroplacental hypoperfusion, & variable deceleration of fetal heart, fetal hypoxia, hypercapnia, perinatal hepatic necrosis or death. Water intoxication with convulsions caused by the inherent antidiuretic effect of oxytocin, is a serious complication that may occur if large doses (40 to 50 milliunits/minute) are infused for long periods. Rapid intravenous bolus injection of oxytocin at doses amounting to several IU may result in acute short lasting hypotension accompanied with flushing & reflex tachycardia.

DOSAGE & ADMINISTRATION

The dosage of oxytocin is determined by the uterine response & must therefore be individualized & initiated at a very low level.

A. Induction or Stimulation of Labor

The initial dose should be 0.5-1 mU/min (equal to 3-6 mL of the dilute oxytocin solution per hour). At 30-60 minute intervals the dose should be gradually increased in increments of 1-2 mU/min until the desired contraction pattern has been established. Once the desired frequency of contractions has been reached & labor has progressed to 5-6 cm dilation, the dose may be reduced by similar increments.

B. Control of Postpartum Uterine Bleeding

- a. **Prevention of postpartum uterine hemorrhage:** The usual dose is 5 IU slowly intravenously or 5 – 10 IU intramuscularly after delivery of the placenta.
- b. **Treatment of postpartum uterine hemorrhage:** 5 IU slowly intravenously or 5-10 IU intramuscularly in severe cases followed by intravenous infusion of a solution containing 5-20 IU of oxytocin in 500 ml of a non-hydrating diluent, run at the rate necessary to manage uterine atony.

C. Cesarean section: 5 IU intramurally or by slow intravenous injection immediately after delivery.

D. Puerperal bleeding, subinvolution of the uterus, lochiometra: 2-5 IU intramuscularly repeated according to individual needs.

STORAGE: Store in a cold place. Do not freeze.

SHELF LIFE: 24 months from the date of manufacture.

PRESENTATION: Partocin 1mL snap off ampoule. Composite pack: 2 x 5 x 1 mL ampoule

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