Rx LITOCIN

(oxytocin injection, USP)

DRUG DESCRIPTION

Litocin (oxytocin injection, USP) is a sterile, clear, colorless aqueous solution of synthetic oxytocin, for intravenous infusion or intramuscular injection. Litocin is a nonapeptide found in pituitary extracts from mammals. It is standardized to contain 10 units of oxytocic hormone/mL and contains 0.5% Chlorobutanol, a chloroform derivative as a preservative, with the pH adjusted with acetic acid. Litocin may contain up to 16% of total impurities. The hormone is prepared synthetically to avoid possible contamination with vasopressin (ADH) and other small polypeptides with biologic activity.

INDICATIONS

Litocin is indicated for the initiation or improvement of uterine contractions, where this is desirable and considered suitable for reasons of fetal or maternal concern, in order to achieve vaginal delivery. It is indicated for (1) induction of labor in patients with a medical indication for the initiation of labor, such as Rh problems, maternal diabetes, preeclampsia at or near term, when delivery is in the best interests of mother and fetus or when membranes are prematurely ruptured and delivery is indicated; (2) stimulation or reinforcement of labor, as in selected cases of uterine inertia; (3) as adjunctive therapy in the management of incomplete or inevitable abortion. In the first trimester, curettage is generally considered primary therapy. In second trimester abortion, oxytocin infusion will often be successful in emptying the uterus. Other means of therapy, however, may be required in such cases.

DOSAGE

The dosage of oxytocin is determined by the uterine response and must therefore be individualized and initiated at a very low level. The following dosage information is based upon various regimens and indications in general use.

Administration

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 and labor has progressed to 5-6 cm dilation, the dose may be reduced by similar increments. Studies of the concentrations of oxytocin in the maternal plasma during Litocin infusion have shown that infusion rates up to 6 mU/min give the same oxytocin levels that are found in spontaneous labor. At term, higher infusion rates should be given with great care, and rates exceeding 9-10 mU/min are rarely required. Before term, when the sensitivity of the uterus is lower because of a lower concentration of oxytocin receptors, a higher infusion rate may be required.

SIDE EFFECTS

Anaphylactic reaction
Postpartum hemorrhage
Cardiac arrhythmia
Fatal afibrinogenemia
Hypertensive episodes
Nausea
Vomiting
Premature ventricular contractions
Pelvic hematoma
Subarachnoid hemorrhage
Hypertensive episodes
Rupture of the uterus

Excessive dosage or hypersensitivity to the drug may result in uterine hypertonicity, spasm, tetanic contraction, or rupture of the uterus.

The possibility of increased blood loss and afibrinogenemia should be kept in mind when administering the drug.

CONTRAINDICATIONS

1. Where there is significant cephalopelvic disproportion;
2. In unfavorable fetal positions or presentations, such as transverse lies, which are undeliverable without conversion prior to delivery;
3. In obstetrical emergencies where the benefit-to-risk ratio for either the fetus or the mother favors surgical intervention;
4. In fetal distress where delivery is not imminent;
5. Where adequate uterine activity fails to achieve satisfactory progress;
6. Where the uterus is already hyperactive or hypertonic;
7. In cases where vaginal delivery is contraindicated, such as invasive cervical carcinoma, active herpes genitalis, total placenta previa, vasa previa, and cord presentation or prolapse of the cord;
8. In patients with hypersensitivity to the drug.

Presentation

Litocin Injection 10 ml containing 10 units of oxytocin per ml

TAJ DRUG WORLD

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Revised November 2010