DESCRIPTION

Pitocin® (Oxytocin Injection, USP) Synthetic is a synthetic hormone which is chemically identical to oxytocin, the endogenous hormone naturally present in the posterior pituitary gland. It is the only source of oxytocin available for parenteral use in the United States. The hormone, the structural formula of which is given below, is prepared synthetically to avoid possible contamination of the drug and its chemical structure and pharmacological properties, it would not be possible to produce unexpected results such as hypertonicity or tetanic contractions when used concomitantly with cyclopropane or halothane anesthesia. In addition, when oxytocin was given three to four hours following prophylactic administration of meperidine, intravenous oxytocin was found not to produce hypertonicity or tetanic contractions in patients without evidence of pre-existing uterine irritability. In contrast, oxytocin given for induction of labor without meperidine in the same situations produced such hypertonicity and tetanic contractions. Therefore, it can be concluded that meperidine is capable of protecting the myometrium against the effects of oxytocin. Further, these properties are thought to be due to the fact that oxytocin and other small polypeptides with biologic activity. Pitocin has the empirical formula C14H26O6N2S2, the molecular weight is 300.47 and is a white or almost white crystalline powder. Pitocin is soluble in water and slightly soluble in alcohol. It is also soluble in pyridine and glacial acetic acid. Pitocin may contain up to 16% of total impurities. The hormone is water sensitive and when reconstituted for intravenous use should be kept continuously by infusion and the solution prepared fresh daily. Pitocin has the following characteristics:

1. Oxytocin has specific molecular properties which differentiate it from other hormone classes.
2. Oxytocin has cyclic properties which can be used to produce hypertonicity or tetanic contractions of the uterus.
3. Oxytocin can produce oxytocin-induced water intoxication has been reported.
4. An increased incidence of maternal death due to hypertension has been noted when oxytocin was used for induction of labor. Overstimulation of the uterus has also been noted when oxytocin was given three to four hours following prophylactic administration of meperidine.

INDICATIONS AND USAGE

Pitocin is indicated to produce hypertonicity or tetanic contractions in patients with pre-existing uterine irritability in those situations in which the myometrium has been protected against the effects of oxytocin. In patients without evidence of pre-existing uterine irritability Pitocin is indicated for maternal deaths due to hypertensive disease of pregnancy. Overstimulation of the uterus to produce unexpected results such as hypertonicity or tetanic contractions when used concomitantly with cyclopropane or halothane anesthesia. In addition, when oxytocin was given three to four hours following prophylactic administration of meperidine, intravenous oxytocin was found not to produce hypertonicity or tetanic contractions in patients without evidence of pre-existing uterine irritability. In contrast, oxytocin given for induction of labor without meperidine in the same situations produced such hypertonicity and tetanic contractions. Therefore, it can be concluded that meperidine is capable of protecting the myometrium against the effects of oxytocin. Further, these properties are thought to be due to the fact that oxytocin and other small polypeptides with biologic activity. Pitocin has the empirical formula C14H26O6N2S2, the molecular weight is 300.47 and is a white or almost white crystalline powder. Pitocin is soluble in water and slightly soluble in alcohol. It is also soluble in pyridine and glacial acetic acid. Pitocin may contain up to 16% of total impurities. The hormone is water sensitive and when reconstituted for intravenous use should be kept continuously by infusion and the solution prepared fresh daily. Pitocin has the following characteristics:

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Due to induced uterine motility:

The following adverse reactions have been reported with synthetic oxytocin, and are based generally on clinical experience with Pitocin®:

- Bradycardia
- Tachycardia
- Hypotension
- Water intoxication with convulsions, anuria, and respiratory depression
- Excessive uterine contraction
- Stroke
- Neonatal seizure
- Neuraxial hematoma

The following adverse reactions have been reported with oxytocin and are based generally on clinical experience with Pitocin®:

- Neonatal retinal hemorrhage
- Neonatal hypertension
- Respiratory distress
- Fetal death
- Hypoxic ischemic encephalopathy
- Intraventricular hemorrhage
- Renal failure
- Premature delivery
- Intracranial hemorrhage
- Intracerebral hemorrhage
- Intrapulmonary shunting
- Atrial septal aneurysms
- Developmental delays

The following adverse reactions have been reported with oxytocin and are based generally on clinical experience with Pitocin®:

- Neonatal death
- Premature rupture of membranes
- Prolonged labor
- Uterine rupture
- Uterine inversion
- Postpartum hemorrhage
- Uteroplacental insufficiency
- Uterine atony

The dosage of oxytocin is determined by the clinical context, and the clinician should consider a variety of factors when deciding upon its use.

Intravenous infusion (drip method) is the preferred route of administration for Pitocin®. The rate of administration should be adjusted as needed to maintain the desired uterine activity pattern. If the uterus is not contracting as desired, the infusion rate should be increased in increments of 0.5 to 1 mU/min (equal to 3 to 6 mL of 10% oxytocin solution) until the desired uterine activity is achieved. Once the desired uterine activity is established, the infusion rate should be adjusted to maintain the desired uterine activity pattern.

Electronic monitoring of uterine activity is essential for optimal administration of Pitocin® and is best achieved by an infusion pump. Accurate control of the rate of infusion is essential to ensure the desired uterine activity pattern is maintained. The infusion rate should be increased in increments of 0.5 to 1 mU/min (equal to 3 to 6 mL of 10% oxytocin solution) until the desired uterine activity is achieved.

If the patient has an intravenous catheter in place, the Pitocin® infusion should be added to the existing solution. If the patient does not have an intravenous catheter, the Pitocin® infusion should be started separately.

Intramuscular administration is not recommended for labor induction due to the risk of uterine, uterine, and uterine contractions.

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