Duratocin

Carbetocin

COMPOSITION

Duratocin Injection: Each ampoule contains 1 ml solution containing Carbetocin INN 100 mcg.

PHARMACOLOGICAL INFORMATION

Duratocin (Carbetocin) is a long-acting synthetic octapeptide analogue of Oxytocin with agonist properties. It can be administered intravenously or intramuscularly as a single dose immediately after the child birth to prevent uterine atony and postpartum hemorrhage (PPH).

The clinical and pharmacological properties of Carbetocin are similar to those of naturally occurring Oxytocin, another posterior pituitary hormone. In in vitro studies, Carbetocin was shown to bind to the Oxytocin receptor with similar affinity as the natural peptide. Carbetocin elicited similar uteronic and galactogogic effects to Oxytocin in animals and in vitro. The Oxytocin receptor content of the uterus is very low in the non-pregnant state, and increases during pregnancy, reaching a peak at the time of delivery. Therefore Carbetocin has no effect on the non-pregnant uterus, and has a potent uterotonic effect on the pregnant and immediate postpartum uterus.

The onset of uterine contraction following Carbetocin administration by either the intravenous or intramuscular route is rapid, with a firm contraction being obtained within 2 minutes in around 90% of patients. The total duration of action of a single intravenous injection of Carbetocin on uterine activity is about one hour suggesting that Carbetocin may act long enough to prevent postpartum hemorrhage in the immediate postpartum period. In comparison to Oxytocin, Carbetocin induces a prolonged uterine response when administered postpartum, in terms of both amplitude and frequency of contractions.

Approximately 0.7% of the Carbetocin dose is eliminated in the unchanged form by the kidney, indicating that Carbetocin, like Oxytocin, is eliminated primarily by non-renal routes.

CLINICAL INFORMATION

Indication

Duratocin Injection is indicated for

- The prevention of uterine atony
- The prevention of excessive bleeding following vaginal and cesarian delivery.

Dosage and Administration
Dose : Single dose immediately after cesarean section (CS) or vaginal delivery
Administration : Recommended as IV/IM injection, a single dose of 100 mcg of Duratocin (Carbetocin) Injection as soon as possible after delivery, preferably before removal of placenta

Contraindication
During pregnancy, Hypersensitivity to Carbetocin or to any of the excipients, Severe hepatic or renal disease.

Precaution
Duratocin Injection should be used cautiously in the presence of epilepsy, migraine, asthma or any state in which a rapid addition to extracellular water may produce hazard for an already overburdened system. Patients with eclampsia and pre-eclampsia should be monitored for changes in blood pressure.

Use in Pregnancy
Category C.

Use in Lactation
Small amounts of Carbetocin have been shown to cross over from plasma into the breast milk of nursing women who were given a 70 mcg dose intramuscularly, between 7 and 14 weeks postpartum. The small amount of Carbetocin transferred into breast milk or colostrum after a single injection, and subsequently ingested by a breast feeding infant, would not be expected to present a significant safety concern. This is due to the fact that Carbetocin would be rapidly degraded by peptidases in the infant gastrointestinal tract.

Drug interaction
No specific drug interactions have been reported with Carbetocin.

Adverse effects
Carbetocin in some cases may associated with nausea, abdominal pain, pruritis, flushing, feeling of warmth and headache.

PHARMACEUTICAL INFORMATION
Storage condition
Store the ampoule in original carton at 2°C to 8°C (Refrigerator), away from light. Keep out of the reach of children.

Presentation & Packing
Duratocin Injection: Each commercial box contains 1 ampoule.

Manufactured By
BEACON®
Pharmaceuticals PLC
Bhaluka, Mymensingh, Bangladesh

LF16302