

COMPOSITION

Arbecin® Injection: Each ampoule contains Carbetocin 100mcg.

PHARMACOLOGICAL INFORMATION

Arbecin® (Carbetocin) is a long-acting synthetic octapeptide analogue of Oxytocin with agonist properties. It can be administered intravenously/ intramuscular as a single dose immediately following delivery by caesarean section under epidural or spinal anaesthesia, to prevent uterine atony and postpartum haemorrhage.

The clinical and pharmacological properties of Carbetocin are similar to those of naturally occurring Oxytocin, another posterior pituitary hormone. In vitro studies, Carbetocin was shown to bind to the Oxytocin receptor with similar affinity as the natural peptide. Carbetocin elicited similar uterotonic 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 IV/Im 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 m by the kidney, indicating that Carbetocin, like Oxytocin, is eliminated primarily by non-real routes.

- Arbecin® is indicated for

 The prevention of uterine atony
 - The prevention of excessive bleeding following delivery of the infant by elective caesarean section under epidural or spinal anaesthesia

DOSAGE & ADMINISTRATION

A single intravenous/intramascular dose of 100mcg of **Arbecin®** (Carbetocin injection) is administered by bolus injection, slowly over 1 minute, only when delivery of the infant has been completed by caesarean section under epidural or spinal anaesthesia.

During pregnancy, hypersensitivity to Carbetocin or to any of the excipients, hepatic or renal disease, cases of pre-eclampsia and eclampsia & serious cardiovascular disorders.

PRECAUTIONS

Carbetocin should be used cautiously in the presence of epilepsy, migraine, asthama or any state in which a rapid addition to extracellular produce hazard for an already overburdened system. Pat water may ients with **Patients** 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 70mcg 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

Intravenous Carbetocin was frequently (10-40% of patients) associated with nausea, abdominal pain, pruritis, flushing, vomiting, feeling of warmth, hypotension, headache and tremor.

STORAGE CONDITION

Store the ampoule in original carton at 2°C to 8°C (refrigerator), away from light. Do not freeze. Keep out of the reach of children.

PRESENTATION

Arbecin® Injection:

Each commercial box contains 1 ampoule.

