

ECBOSUERE

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for ECBOSUERE (Carbetocin Injection 100 mcg/ml) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES: Carbetocin binds to oxytocin receptors present on the smooth musculature of the uterus, resulting in rhythmic contractions of the uterus, increased frequency of existing contractions, and increased uterine tone.

INDICATIONS: ECBOSUERE indicated for the prevention of postpartum haemorrhage due to uterine atony.

DOSAGE AND ADMINISTRATION: As directed by the Physician. Tablets should be taken orally.

CONTRAINDICATION: During pregnancy and labour before delivery of the infant, Carbetocin must not be used for the induction of labour, Hypersensitivity to carbetocin, oxytocin or to any of the excipients, Hepatic or renal disease, Serious cardiovascular disorders, Epilepsy

WARNINGS & PRECAUTIONS: Carbetocin is intended for use only at well-equipped specialist obstetrics units with experienced and qualified staff available at all times; The use of carbetocin at any stage before delivery of the infant is not appropriate because its uterotonic activity persists for several hours. This is in marked contrast to the rapid reduction of effect observed after discontinuation of an oxytocin infusion; In case of persistent vaginal or uterine bleeding after administration of carbetocin the cause must be determined. Consideration should be given to causes such as retained placental fragments, perineal, vaginal and cervix lacerations, inadequate repair of the uterus, or disorders of blood coagulation; Carbetocin is intended for single administration only, intramuscular or intravenous. In case of intravenous administration, it must be administered slowly over 1 minute. In case of persisting uterine hypotonia or atonia and the consequent excessive bleeding, additional therapy with another uterotonic should be considered. There are no data on additional doses of carbetocin or on the use of carbetocin following persisting uterine atony after oxytocin; In general, carbetocin should be used cautiously in the presence of migraine, asthma and cardiovascular disease or any state in which a rapid addition to extracellular water may produce hazard for an already overburdened system. The decision of administering carbetocin can be made by the physician after carefully weighing the potential benefit carbetocin may provide in these particular cases.

DRUG INTERACTIONS: During clinical trials, carbetocin has been administered in association with a number of analgesics, spasmolytics and agents used for epidural or spinal anaesthesia, and no drug interactions have been identified; Specific interaction studies have not been undertaken; Since carbetocin is closely related in structure to oxytocin, the occurrence of interactions known to be associated with oxytocin cannot be excluded.

Severe hypertension has been reported when oxytocin was given 3 to 4 hours following prophylactic administration of a vasoconstrictor in conjunction with caudal-block anaesthesia.

During combination with ergot-alkaloids, such as methylergometrine, oxytocin and carbetocin may enhance the blood pressure enhancing effect of these agents. If oxytocin or methylergometrine are administered after carbetocin there may be a risk of cumulative exposure.

Since it has been found that prostaglandins potentiate the effect of oxytocin, it is expected that this can also occur with carbetocin. Therefore, it is not recommended that prostaglandins and carbetocin be used together. If they are concomitantly administered, the patient should be carefully monitored.

Some inhalation-anesthetics, such as halothane and cyclopropane may enhance the hypotensive effect and weaken the effect of carbetocin on the uterus. Arrhythmias have been reported for oxytocin during concomitant use.

ADVERSE REACTIONS: Headache, tremor, Hypotension, Nausea, abdominal pain, Anaemia, Pruritus, Feeling of warmth, Tremor, Flushing, Dyspnoea, Urinary retention, Chest pain, Dizziness Chills, pain, Back pain

MARKETED BY:



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IN/ECBOSUERE 100 mcg/ml/Feb-2023/01/ABPI

(Additional information is available on request)