

Prescribing Information: Pabal® (carbetocin) 100 micrograms in 1ml solution for injection.

Please consult the full Summary of Product Characteristics before prescribing.

Name of Product: Pabal® 100 micrograms in 1ml solution for injection.

Composition: Pabal® contains 100 micrograms/ml carbetocin.

Indication: Prevention of postpartum haemorrhage due to uterine atony.

Dosage and administration: Caesarean section under epidural or spinal anaesthesia 1ml of Pabal® by intravenous injection. Vaginal delivery 1ml of Pabal® by intramuscular or intravenous injection. Intravenous injection: administer slowly, over one minute. Carbetocin must only be administered after delivery of the infant, and as soon as possible after delivery, preferably before the delivery of the placenta.

Contraindications: Pabal® is contraindicated in the following conditions: during pregnancy and labour before delivery of the infant, it must not be used for induction of labour; hypersensitivity to carbetocin or oxytocin; hepatic or renal disease; patients with serious cardiovascular disorders; epileptic patients.

Special warnings and Precautions: Use only in well equipped specialist obstetric units with experienced and qualified staff available at all times. Use of Pabal® at any stage before delivery of the infant is not appropriate because its uterotonic activity persists for several hours. In case of persistent vaginal or uterine bleeding after administration, the cause must be determined and considerations should include: retained placental fragments, perineal, vaginal and cervix lacerations, inadequate repair of uterus, disorders of blood coagulation. Intended for single administration only. In case of persisting uterine hypotonia or atonia and consequent excessive bleeding, additional therapy with another uterotonic should be considered. Animal studies have shown carbetocin to possess some antidiuretic activity; therefore the possibility of hyponatraemia cannot be excluded, particularly in patients also receiving large volumes of intravenous fluids. Use with caution in the presence of: migraine, asthma, cardiovascular disease or any state in which a rapid addition to extracellular water may produce a hazard for an already overburdened system. No data is available on the use of carbetocin in patients with eclampsia. Patients with eclampsia and pre-eclampsia should be carefully monitored. Specific studies have not been undertaken in gestational diabetes mellitus.

Side Effects: Adverse events of the same type and frequency as those observed with oxytocin when administered for the same indication. Very common adverse events include: headache, tremor, hypotension, flushing, nausea, abdominal pain, pruritis, feeling of warmth. Common adverse events include: anaemia, dizziness, chest pain, dyspnoea, metallic taste, vomiting, back pain, chills and pain. Please consult the full Summary of Product Characteristics for further information about side effects.

Special Precautions for Storage: Store below 30°C. Protect from light. Do not freeze.

Presentation: Packs of 5 vials. Each vial contains 1 ml of carbetocin solution for injection.

Marketing Authorisation Number: 03194/0058. **Marketing Authorisation Holder:** Ferring Pharmaceuticals Ltd., Drayton Hall, Church Road, West Drayton, UB7 7PS, UK.

Legal Category: POM. **Basic NHS Price:** Packs 5 x 1ml ready-to-use vials: £88.20

Date of Preparation: December 2019. **PI Job Code:** UK-PAB-1900004

Pabal® is a registered trademark.

Adverse events should be reported. Reporting forms and information can be found at

www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to Ferring Pharmaceuticals Ltd.

Tel: 0800 111 4126. Email: medical.uk@ferring.com