Prescribing Information: Pabal® (carbetocin) 100 micrograms in 1ml solution for injection.
Please consult the full Summary of Product Characteristics before prescribing.
Name: 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. Must be given under adequate medical supervision in a hospital. Intended for single use only – do not give further doses.
Contraindications: During pregnancy and labour before delivery of the infant; it must not be used for induction of labour; hypersensitivity to carbetocin, oxytocin or any excipients; hepatic or renal disease; 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. Consider: 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, consider additional therapy with another uterotonic. Animal studies have shown some antidiuretic activity; therefore the possibility of hyponatraemia cannot be excluded, particularly in patients also receiving large volumes of intravenous fluids – be aware of early signs of drowsiness, listlessness and headache to prevent convulsions and coma. 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 use in patients with eclampsia. Carefully monitor patients with eclampsia and pre-eclampsia. Specific studies have not been undertaken in gestational diabetes mellitus.
Interactions: Due to structural similarity to oxytocin, occurrence of interactions known to be associated with oxytocin cannot be excluded - severe hypertension reported when oxytocin given 3-4 hours following prophylactic administration of a vasoconstrictor in conjunction with caudal-block anaesthesia. During combination with ergot-alkaloids e.g. methylergometrine, oxytocin and carbetocin may enhance the blood pressure enhancing effects of these agents - if oxytocin or methylergometrine are administered after carbetocin, there may be a risk of cumulative exposure. It is not recommended that prostaglandins and carbetocin be used together due to prostaglandins potentially potentiating the effect of carbetocin - if used together, carefully monitor the patient. Some inhalation-anaesthetics e.g. halothane, may enhance the hypotensive effect and weaken the effect of carbetocin on the uterus. Arrhythmias have been reported for oxytocin during concomitant use.
Pregnancy: Contraindicated during pregnancy and must not be used for induction of labour. Breastfeeding: Does not need to be restricted after the use of carbetocin.
Side Effects: Very common, common and serious uncommon, rare and frequency unknown adverse events are reported here. Please consult the Summary of Product Characteristics for full information. Intravenous administration (based on caesarean section studies): Very common: headache, tremor, hypotension, flushing, nausea, abdominal pain, pruritus, feeling of warmth. Common: Anaemia, dizziness, chest pain, dyspnoea, metallic taste, vomiting, back pain, chills, pain. Serious unknown frequency: tachycardia; Serious unknown frequency (reported with oxytocin): bradycardia, arrhythmia, myocardial ischaemia, QT prolongation. Intramuscular administration (based on vaginal delivery studies): Serious uncommon: Anaemia, tachycardia, hypotension, chest pain. Serious rare: Dyspnoea, urinary retention. Serious unknown frequency (reported with oxytocin): bradycardia, arrhythmia, myocardial ischaemia, QT prolongation.
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: July 2023. **PI Job Code: UK-PAB-2300001**
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**