PABAL®

(Carbetocin Injection)
1 mL ampoule - 100 µg/mL Injection
For Intravenous Use Only
THERAPEUTIC CLASSIFICATION
Uterotonic Agent

201191 201191

COMPOSITION

Each ampoule contains 100 µg (0.1 mg) of carbetocin, 9 mg sodium chloride, glacial acetic acid (6-14 µg) and water for injection q.s. to 1 mL. Ampoules are clear glass with a white identification ring and a blue dot indicating the cut area.

INDICATIONS AND CLINICAL USE

Prevention of uterine atony and excessive bleeding following delivery of the infant by Caesarean section under epidural or spinal anaesthesia.

DOSAGE AND ADMINISTRATION

Withdraw 1 ml of PABAL/DURATOCIN/LONACTENE containing 100 micrograms carbetocin and administer only by intravenous injection, under adequate medical supervision in a hospital.
A single dose of carbetocin must be administered only after delivery of the infant
by Caesarean section. It should be given as soon as possible after delivery, preferably before removal of the placenta. No further doses of carbetocin should be administered.

CONTRAINDICATIONS

Pregnancy and labour before delivery of the infant.
Induction of labour.
Serious cardiovascular disorders.
Hypersensitivity to carbetocin or oxytocin.

WARNINGS

Special warnings and precautions for use:

1. Use only at well equipped specialist obstetrics units.
2. Uterine bleeding after administration of carbetocin the cause must be determined.
3. Carbetocin is intended for single administration only.
4. The risk of water intoxication cannot be excluded.
5. Carbetocin should be used cautiously in the presence of epilepsy, migraine, asthma and cardiovascular disease
6. Patients with eclampsia and pre-eclampsia should be monitored for changes in blood pressure.
7. Studies have not been undertaken in gestational diabetes mellitus.

PREGNANCY & LACTATION

Carbetocin is contraindicated during pregnancy for the induction of labour.
Small amounts of carbetocin have been shown to pass from plasma into breast
milk of nursing women. The small amounts transferred into colostrum or breast milk after a single injection of carbetocin, and subsequently ingested by the infant are assumed to be degraded by enzymes in the gut.

DRUG INTERACTIONS

No specific drug interactions have been reported with carbetocin. However, since carbetocin is closely related in structure to oxytocin, it is possible that some of the same drug interactions could occur. Severe hypertension has been reported when oxytocin was given 3-4 hours following prophylactic administration of a vasoconstrictor in conjunction with caudal block anesthesia. Cyclopropane anesthesia may modify oxytocin's cardiovascular effects, so as to produce unexpected results such as hypotension. Matemal sinus bradycardia with abnormal atrioventricular rhythms has also been noted when oxytocin was used concomitantly with cyclopropane anesthesia.

ADVERSE REACTIONS

The adverse events oberved with carbetocin during the clinical trials were of the same type and frequency as the adverse events observed with oxytocin when administered after ceasarean section under spinal or epidural anaesthesia

System Organ Class	Very common ≥ 1/10	Common ≥ 1/100 and < 1/10
Blood and the lymphatic system disorders		Anaemia
Nervous system disorders	Headache, tremor	Dizziness
Vascular disorders	Hypotension, flushing	
Respiratory, thoracic and mediastinal disorders		Chest pain, dyspnoea
Gastrointestinal disorders	Nausea, abdominal pain	Metallic taste, Vomiting
Skin and subcutaneous tissue disorders	Pruritus	
Musculoskeletal and connective tissue disorders		Back pain
General disorders and administration site conditions	Feeling of warmth	Chills, pain

In the clinical trials sweating and tachycardia were reported as sporadic cases.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Overdosage of carbetocin may produce uterine hyperactivity whether or not due to hypersensitivity to this agent. At single doses up to 800 micronrams tachycardia was observed.

Overdosage of oxytocin may lead to hyponatraemia and water intoxication in severe cases, especially when associated with excessive concomitant fluid intake.

As carbetocin is an analogue of oxytocin, the possibility of a similar event cannot be excluded.

Signs of overdose may be the symptoms arising from water intoxication and uterine hyperactivity.

Treatment of overdosage of carbetocin consists of symptomatic and supportive therapy.

STABILITY AND STORAGE RECOMMENDATIONS

PABAL (carbetocin injection) must be stored at refrigerator temperature (2-8°C). PABAL should not be frozen. Once the ampoule has been opened, the product should be used immediately.

AVAILABILITY OF DOSAGE FORMS

PABAL (carbetocin injection) is available in 1 mL ampoules. Each ampoule contains 100 µg carbetocin. Boxes contain 5 ampoules each.

INSTRUCTIONS FOR OPENING AMPOULES

1. Hold ampoule with blue dot pointing upwards.
   Shake or tap ampoule to empty the tip.
2. With blue dot pointing upwards, snap off tip by forcing it downwards.

Manufacturer: DRAXIS Pharma, a division of DRAXIS Specialty Pharmaceuticals Inc. Montreal, Canada.
Marketing Authorization Holder: Ferring GmbH
Kiel, Germany
Date of revision: June 2006

FERRING
PHARMACEUTICALS

THIS IS A MEDICINE
- A MEDICINE IS A PRODUCT WHICH AFFECTS YOUR HEALTH, AND ITS CONSUMPTION CONTRARY TO INSTRUCTIONS IS DANGEROUS FOR YOU.
- STRICTLY FOLLOW THE DOCTOR'S PRESCRIPTION, THE METHOD OF USE AND THE INSTRUCTIONS OF THE PHARMACIST WHO SOLD THE MEDICINE.
- THE DOCTOR AND THE PHARMACIST ARE EXPERTS IN MEDICINE, ITS BENEFITS AND RISKS.
- DO NOT BY YOURSELF INTERRUPT THE PERIOD OR TREATMENT PRESCRIBED FOR YOU.
- DO NOT REPEAT THE SAME PRESCRIPTION WITHOUT CONSULTING YOUR DOCTOR.
- KEEP THE MEDICINE OUT OF REACH OF CHILDREN.

Council of Arab Health Ministers
Union of Arab Pharmacists