



# Duratocin<sup>®</sup>

CARBETOCIN



## DOSAGE & ADMINISTRATION GUIDE

<b>INDICATION<sup>1</sup></b>	<ul style="list-style-type: none"> <li>▪ DURATOCIN<sup>®</sup> (carbetocin injection) is indicated for the prevention of uterine atony and postpartum hemorrhage following cesarean section under epidural or spinal anesthesia</li> </ul>
<b>DOSAGE AND ADMINISTRATION<sup>1</sup></b>	<ul style="list-style-type: none"> <li>▪ A single intravenous dose of 100 mcg (1 mL) of DURATOCIN<sup>®</sup> is administered by bolus injection, slowly over 1 minute</li> <li>▪ Administer only when delivery has been completed by cesarean section under epidural or spinal anesthesia</li> <li>▪ Can be administered either before or after delivery of the placenta</li> </ul>
<b>EMERGENCY AND ELECTIVE USE</b>	
<b>EMERGENCY USE<sup>1</sup></b>	<ul style="list-style-type: none"> <li>▪ In emergency cesarean section patients, DURATOCIN was significantly lower vs. oxytocin in:<sup>1*</sup> <ul style="list-style-type: none"> <li>– Postpartum hemorrhage (primary endpoint) 2% vs. 13% oxytocin (p=0.03)</li> <li>– Estimated blood loss 689 ± 580 vs. 1027 ± 659 oxytocin (p=0.002)</li> <li>– Need for transfusion 0 vs. 16% oxytocin (p=0.04)</li> </ul> </li> <li>▪ Only 2% of DURATOCIN patients vs. 71% of oxytocin needed additional uterotonics (p=0.002)<sup>1</sup></li> <li>▪ Haemoglobin levels before and 24-h postpartum were similar<sup>1</sup></li> <li>▪ The uterine contractility was better in DURATOCIN patients at 2-h and 12-h postpartum (p&lt;0.05)<sup>1</sup></li> </ul>
<b>EMERGENCY AND ELECTIVE USE<sup>1</sup></b>	<ul style="list-style-type: none"> <li>▪ DURATOCIN was significantly better vs. oxytocin in reducing the need for additional oxytocic intervention (primary endpoint)<sup>1†</sup> <ul style="list-style-type: none"> <li>– 33% reduction vs. 45% for oxytocin (p=0.023)</li> </ul> </li> <li>▪ No significant differences were seen between DURATOCIN and oxytocin in:<sup>1</sup> <ul style="list-style-type: none"> <li>– Postpartum hemorrhage with blood loss &gt;1000 mL, estimated intraoperative blood loss, difference in haemoglobin, uterine tone and incidence of blood transfusions</li> </ul> </li> </ul>

### DURATOCIN INFORMATION

#### Indications and Clinical Use:

DURATOCIN (carbetocin injection) is indicated for the prevention of uterine atony and postpartum hemorrhage following cesarean section under epidural or spinal anesthesia.

DURATOCIN has not been studied in cases involving patients with a history of hypertension, known coagulopathy or evidence of liver, renal or endocrine disease. Appropriate studies have not been undertaken and doses have not been established in women following labour or vaginal delivery.

#### Contraindications:

Due to its long duration of action relative to oxytocin, uterine contractions produced by carbetocin cannot be stopped by simply discontinuing the medication.

DURATOCIN should not be administered:

- In pregnancy - prior to delivery of the infant for any reason, including elective or medical induction of labour
- In patients with a history of hypersensitivity to oxytocin or carbetocin
- In patients with serious cardiovascular disorders
- In children

#### Relevant Warnings and Precautions:

- Use only at well-equipped specialist obstetrics units
- Some patients may not have an adequate uterine contraction after a single injection - administration should not be repeated and more aggressive

treatment with other uterotonic drugs like oxytocin or ergometrine is warranted

- In persistent bleeding, the presence of retained placental fragments, coagulopathy, or trauma to the genital tract should be ruled out
- Due to antidiuretic effects, risk of water intoxication cannot be excluded
- Monitor patients with eclampsia and pre-eclampsia for changes in blood pressure
- Use with extreme caution in patients with cardiovascular disease, especially coronary artery disease
- Not studied in gestational diabetes mellitus
- Use cautiously in migraine and epilepsy
- Use cautiously in asthma
- Nursing women - the small amount of Duratocin transferred into breast milk or colostrum after a single 70 mcg dose injection would not be expected to present a significant safety concern - no sufficient evidence to determine if it stimulates milk let-down
- Not recommended for Pediatrics (< 18 years) or Geriatrics (> 65 years)

#### For more information:

Please consult product monograph [https://pdf.hres.ca/dpd\\_pm/00037331.PDF](https://pdf.hres.ca/dpd_pm/00037331.PDF) for important information relating to adverse reactions, drug interactions and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling 1-866-384-1314.

\*A randomised, active-controlled, double-blind, parallel-group trial compared DURATOCIN 100 mcg IV (n=188) to oxytocin 5 IU IV (n=189) in healthy pregnant women undergoing elective or emergency cesarean section under regional anesthesia. Primary endpoint was the incidence of need for additional oxytocin intervention.

†A randomised, active-controlled, double-blind, double dummy, parallel-group trial compared the efficacy and safety of DURATOCIN 100 mcg IV (n=90) to oxytocin 20 IU - 8 h IV infusion (n=90) in obese (BMI>30), nulliparous, pregnant women undergoing emergency cesarean section. Primary endpoint was major primary postpartum hemorrhage defined as blood loss ≥ 1000 mL within 24 h of delivery.

Reference: 1. <sup>®</sup>DURATOCIN<sup>®</sup> Product Monograph. Ferring Inc. November 30, 2016.

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