

*For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.*

## Carboprost Tromethamine Injection I.P.

### **ENDOPROST**

#### **125mcg / 250mcg**

For Intramuscular use only

#### **Description :**

**ENDOPROST** is a clear colourless sterile aqueous solution of Carboprost Tromethamine for Intramuscular Injection. Carboprost is a synthetic 15 methyl analogue of naturally occurring prostaglandin F2 $\alpha$ .

Carboprost Tromethamine is chemically a salt of (5Z,13E)-(8R,9S,11R,15S)-9,11,15-trihydroxy-15-methyl-5,13-prostadien-1-oic acid with 2-amino-2-hydroxymethyl-1,3-propanediol. The molecular formula is C<sub>25</sub>H<sub>47</sub>O<sub>8</sub>N and has a molecular weight of 489.64. It is a white to slightly off-white crystalline powder and is soluble in water.

#### **Each ml of ENDOPROST contains :**

Carboprost Tromethamine I.P. equivalent to 250 mcg of Carboprost as an aqueous solution containing Benzyl Alcohol B.P. and Sodium Chloride I.P. pH is adjusted with Sodium Hydroxide I.P. and or Hydrochloric acid I.P.

#### **Clinical Pharmacology :**

Carboprost is a Uterine stimulant and is used for the control of post partum haemorrhage (PPH). Carboprost Tromethamine when administered as an intramuscular injection arrests intractable atonic post partum hemorrhage by inducing myometrial contractions. This haemostasis produced by Carboprost Tromethamine at the site of placentation minimizes the third stage blood loss and thereby reduces the maternal mortality and morbidity. Also, Carboprost tromethamine when administered prophylactically at the time of labour, because of its uterine stimulant activity it complements the physiological processes during labour, resulting in reduction of the duration of third stage and hence minimize post partum blood loss.

#### **Indications and usage :**

**ENDOPROST** is indicated for the treatment of post partum haemorrhage, especially due to uterine atony which has not responded to conventional methods of management.

**ENDOPROST** (125 - 250 mcg) may be used prophylactically by intramuscular injection at the birth of anterior shoulder in patients with following risks.

- Grand multipara
- Pre-eclampsia
- Rapid or prolonged labour
- Placental abnormalities
- Previous uterine surgery
- History of PPH
- History of retained placenta
- Over distention of uterus

**Contraindications :**

1. Hypersensitivity to carboprost tromethamine.
2. Acute pelvic inflammatory disease.
3. Patients with active cardiac, pulmonary, renal or hepatic disease.

**Precautions :**

**ENDOPROST** should be administered cautiously in patients with a history of asthma, hypo or hypertension, cardiovascular, renal or hepatic disease, anemia, jaundice, diabetes, or epilepsy.

**ENDOPROST** is not recommended in patients having chorioamnionitis during labour as it may have an inhibitory effect on **ENDOPROST** activity.

**ENDOPROST** should be used with caution in patients with compromised or scarred uterus.

**Adverse effects :**

The most frequent adverse effects observed are due to its contractile effect on smooth muscle, which are transient and reversible on cessation of therapy. These include vomiting, diarrhoea, hyperpyrexia and flushing. The incidences of these common side effects during high dose treatment of **ENDOPROST** can be minimized by pretreatment or co-administration of antiemetic and antidiarrheal drugs.

**Dosage and Administration :**

1. As a prophylactic treatment for the control of post partum haemorrhage :

**ENDOPROST** at a dose equivalent to 125 - 250 mcg of Carboprost should be given intramuscularly at the delivery of the anterior shoulder of fetus.

2. For Refractory Post Partum Haemorrhage :

**ENDOPROST** at a dose equivalent to 250 mcg of Carboprost is given by deep intramuscular injection at interval of about 90 minutes. The interval may be reduced if necessary but should not be less than 15 minutes. The total dose should not exceed 2000 mcg (8 ampoules of 250 mcg).

**Presentation :**

**ENDOPROST** is available in pack sizes of 0.5ml and 1ml.

**ENDOPROST - 0.5ml Vial :**

Each 0.5ml containing Carboprost Tromethamine equivalent to 125 mcg of Carboprost.

**ENDOPROST - 1ml Vial :**

Each ml containing Carboprost Tromethamine equivalent to 250 mcg of Carboprost.

**ENDOPROST** should be stored in a refrigerator (2°C - 8°C). Do not freeze.

Manufactured in India by :

**BHARAT SERUMS AND VACCINES LIMITED**

Plot No. K-27, Additional M.I.D.C., Ambernath (E) - 421 501