SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal product:

1.1 Product name

ENDOPROST

Carboprost Tromethamine Injection U.S.P.

1.2 Strength

250 mcg

1.3 Pharmaceutical dosage form

Injection

2. Qualitative and Quantitative compositions

Name of the component	Specification	Quantity / 1 ml	Justification for use of Ingredient
Carboprost Tromethamine *Equivalent to Carboprost	U.S.P.	250 mcg	Active Pharmaceutical Ingredient
Benzyl Alcohol	U.S.P.	9.45 mg	Preservative
Sodium Chloride	U.S.P.	9.0 mg	Isotonic agent
Sodium Hydroxide	U.S.P.	q.s. for PH adjustment	For pH Adjustment
Hydrochloric Acid	U.S.P.	q.s. for PH adjustment	For pH Adjustment
Water for Injection	U.S.P.	q.s.	Vehicle

***To be dispensed on 100 % potency basis**

Note: U.S.P. United States Pharmacopoeia

3. Pharmaceutical form:

Liquid Injection

4. Clinical Particulars:

4.1 Therapeutic Indications:

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

Endoprost (125 mcg-250 mcg) may be used prophylactically by Intramuscular Injection at the birth of anterior shoulder in patients with the 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.

4.2 Posology and method of administration

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

Endoprost at a dose equivalent to 125 mcg-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 less than 15 minutes. The total dose should not to exceed 2000mcg (8 ampoules of 250mcg)

4.3 Contra-Indications

1. Hypersensitivity to Carboprost Tromethamine
2. Acute Pelvic Inflammatory disease.
3. Patients with active cardiac, pulmonary, renal or hepatic disease.

4.4 Special warning and precautions for use

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 scatter uterus.

4.5 Interaction with other drugs, other forms of interactions:

No drug/drug interaction studies have been conducted for Endoprost in humans.

4.6 Use in pregnancy and lactation

None reported

4.7 Effects on ability to drive and operate machine

None well documented for these groups of patients

4.8 Undesirable effects

The most frequent adverse effect 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.

4.9 Overdoses

None reported

5. Pharmacological properties :

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

6. Pharmaceutical particulars :

6.1 List of Excipients:

Excipients	Pharmacopoeial claim
Benzyl Alcohol	U.S.P.
Sodium Chloride	U.S.P.
Sodium Hydroxide	U.S.P.
Hydrochloric Acid	U.S.P.
Water for Injection	U.S.P.

U.S.P.- United States Pharmacopoeia

6.2 Incompatibilities:

The product is stable and there is no incompatibility amongst excipients

6.3 Shelf-life:

24 months from the date of manufacturing.

6.4 Special precaution for storage:

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

6.5 Nature and contents of container:

The clear colourless solution is packed in U.S.P. Type I Tubular vial of 2 ml and is sealed with rubber bung & Aluminium Flip off seal.
One carton containing one vial with pack insert.

7. Marketing authorization holder :

Bharat Serums & Vaccines Ltd.
17th Floor, Hoechst House,
Nariman Point,
Mumbai – 400 021
India.

8. Marketing authorization number :

Not Applicable

9. Date of first authorization / renewal of authorization :

Not Applicable

10. Date of revision of the text :

Not Applicable