

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

## **Carboprost Tromethamine Injection IP**

### **Prostodin™ 125**

### **Prostodin 250**

Prostodin sterile solution contains the tromethamine salt (15S) - 15 - methyl analogue of naturally occurring Prostaglandin F<sub>2α</sub> suitable for intramuscular injection.

### **COMPOSITION**

Prostodin 125: Each 0.5 ml contains Carboprost tromethamine IP equivalent to 125 mcg Carboprost.

Prostodin 250: Each 1.0 ml contains Carboprost tromethamine IP equivalent to 250 mcg Carboprost.

### **CLINICAL PHARMACOLOGY**

Prostodin administered intramuscularly is highly effective in arresting intractable atonic postpartum hemorrhage. The mechanism of haemostasis appears to be predominantly through induction of myometrial contractions.

Prostodin (125-250 mcg) prophylactically at the time of delivery complements physiological processes during labour and results in reduction in the duration of third stage of labour, ensures faster expulsion of placenta and minimizes postpartum blood loss.

### **INDICATIONS AND USAGE**

Prostodin is indicated for treatment of postpartum hemorrhage, especially due to uterine atony. It results in cessation of life threatening bleeding and avoidance of emergency surgery.

Prostodin (125-250 mcg) may be used prophylactically, in high-risk patients by intramuscular injection at the birth of anterior shoulder of the fetus.

### **CONTRAINDICATIONS AND PRECAUTIONS**

Contraindications include hypersensitivity to Prostaglandins, acute pelvic inflammatory disease and patients with active cardiac, pulmonary, renal or hepatic disease. Since chorioamnionitis during labour may have an inhibitory effect on the uterine response to Prostodin as reported for other oxytocics, its use is not recommended in such cases. As with other oxytocics, Prostodin should be used with caution in patients with scarred uterus.

### **ADVERSE REACTIONS**

The adverse effects of Prostodin are generally dose related, transient and reversible when therapy ends. The most frequent adverse reactions observed are related to its contractile effects on smooth muscle i.e., vomiting, diarrhea, hyperpyrexia and flushing.

### **DOSAGE AND ADMINISTRATION**

Prophylactic use for control of Postpartum Hemorrhage

Prostodin (125-250 mcg) intramuscularly at the delivery of the anterior shoulder of the fetus.

Refractory Postpartum Hemorrhage

Prostodin (250 mcg) to be given deep intramuscularly. The majority of successful cases (73%) responded to a single injection in clinical trials. In some selected cases, multiple dosing at an interval of 30-90 minutes may be required. The total dose should not exceed 2 mg (8 ampoules) per day.

### **PRESENTATION**

Prostodin™ 125: 0.5 ml snap off ampoule; Prostodin 250: 1.0 ml snap off ampoule.

Prostodin should be stored in a refrigerator at 2°-8°C.