

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

## **Cerviprime™ Gel**

Cerviprime Gel contains dinoprostone, the naturally occurring form of prostaglandin E<sub>2</sub> (PGE<sub>2</sub>).

### **COMPOSITION**

Each 3.0g Cerviprime gel contains: Dinoprostone 0.5mg

### **CLINICAL PHARMACOLOGY**

Cerviprime (dinoprostone) gel administered endocervically may stimulate the myometrium of gravid uterus to contract, similar to contractions seen in term uterus during labour. Dinoprostone also has a local cervical effect in initiating softening, effacement, and dilation of cervix (cervical ripening) and allows evacuation of uterine contents.

### **INDICATION AND USAGE**

Cerviprime gel is used for pre-induction cervical ripening and dilatation in pregnant women at or near term with unfavourable induction features such as poor Bishop Score.

### **CONTRAINDICATIONS AND PRECAUTIONS**

Patients in whom oxytocic drugs are generally contraindicated such as history of caesarean section or major uterine surgery, difficult labour and/or traumatic delivery, previous or current pelvic inflammatory disease; presence of cephalopelvic disproportion; grand multiparae; hypersensitivity to prostaglandin's; placenta previa or unexplained vaginal bleeding.

Dinoprostone should be administered by physicians in a hospital that can provide immediate intensive care and acute surgical facilities. During use, uterine activity, foetal status, and dilation and effacement of cervix should be carefully monitored. Caution should be exercised in using it in patients with asthma, hypertension or glaucoma. Caution should be exercised in the administration of Cerviprime gel in patients with ruptured membranes.

### **ADVERSE REACTIONS**

Cerviprime gel is generally well-tolerated. The reported adverse events include uterine contractile abnormality, gastro-intestinal effects, back pain and fever in the maternal women and changes in foetal heart rate. Cerviprime gel can augment the activity of other oxytocics; hence their concomitant use is not recommended.

### **DOSAGE AND ADMINISTRATION**

Cerviprime gel should be brought to room temperature (15°-30°C) prior to its administration. Please refer to full prescribing information for detailed technique of administration of Cerviprime gel. Following administration of Cerviprime gel, the patient should remain in supine position for 15-30 minutes to minimize leakage from the cervical canal. The recommended repeat dose is 0.5 mg dinoprostone, at a dosing interval of 6 hours with maximum recommended cumulative dose for a 24-hour period being 1.5 mg. The need for additional dose and the interval must be determined by the attending physician, based on clinical course. Overdosage with Cerviprime gel may result in uterine hypercontractility and hypertonus.

### **PRESENTATION**

Cerviprime Gel-Prefilled syringe of 3g. Cerviprime Gel should be stored in a refrigerator at 2°-8°C.