

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

Primiprost™ Tablets

Primiprost tablets contain dinoprostone (naturally occurring prostaglandin [PGE₂]) for oral administration.

COMPOSITION

Each tablet contains: Dinoprostone 0.5mg.

CLINICAL PHARMACOLOGY

Oral dinoprostone may stimulate the myometrium of gravid uterus to contract, similar to contractions seen in the term uterus during labour. Dinoprostone aids in evacuation of uterine contents by decreasing cervical resistance and increasing myometrial activity.

INDICATIONS AND USAGE

PRIMIPROST tablets are indicated for induction and augmentation of labour at or near term.

CONTRAINDICATIONS

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

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 dinoprostone tablets in patients with ruptured membranes.

DOSAGE AND ADMINISTRATION

Primiprost tablets are administered orally for induction of labour, 0.5 mg, followed by 0.5–1 mg at hourly intervals. The maximum recommended dose is 1.5 mg of dinoprostone.

ADVERSE REACTIONS

The reported adverse events include nausea, vomiting, diarrhoea, fever and flushing, and constriction of the airways. Maternal and Foetal effects such as uterine contractile abnormality and changes in foetal heart rate, respectively may occur. Dinoprostone can augment activity of other oxytocics; hence their concomitant use is not recommended.

PRESENTATION

Primiprost - strip of 4 tablets. Primiprost tablets should be stored in a cool, dry place.