During the use of PRIMIGYN® Gel, uterine activity, fetal status, cervical dilation and effacement should be carefully monitored to detect any undesirable effects like hypertonus myometrial contractions or fetal distress. In the event where high tone of myometrial contractions are sustained, the possibility of uterine rupture should be borne in mind.

**PRECAUTIONS**

- In the presence of bladder neck lesions are reported with the use of PRIMIGYN® Gel. Occasional cases of uterine contractions or effacement and/or uterine rupture have also been reported.
- Uterine contractile abnormalities with or without fetal distress have also been reported.
- Intrapartum fetal distress are also reported.

**WARNING :**

- Post operative infections.
- Haemorrhage.
- Asthma or history of asthma.
- Seizure disorder.

**DESCRIPTION :**

Gel contains 0.5 mg Dinoprostone BP per 3.0 g gel in a syringe with a catheter for endocervical application.

**DOSAGE AND ADMINISTRATION**

The entire contents of the syringe should be administered into the cervical canal just below the level of the internal os using the catheter which is included. The patient should be instructed to remain recumbent or lying down on one side for at least 30 minutes.

**ADVERSE REACTIONS**

TM

Dinoprostone Gel is a naturally occurring form of prostaglandin E2 (PGE2).

Dinoprostone (PGE2) is a naturally occurring biologically active compound that is found in low concentrations in the tissues of the body. It is rapidly metabolized in the tissues of synthesis (half-life estimated to be 3.5 minutes).

**OVERDOSAGE :**

TM

No life threatening adverse reactions are reported with the use of PRIMIGYN® Gel. Occasional cases of uterine contractions or effacement and/or uterine rupture are reported.

**MISCELLANEOUS**

- A single dose of induction of labour should be given on the basis of a gestational assessment.
- A site of application should be chosen which is away from previous surgery or scarring.

**INDICATION:**

- Induction of labour
- Premature rupture of the membranes
- Cervical ripening
- Fetal distress
- Failed induction of labour

**PHARMACOLOGY :**

Dinoprostone (PGE2) is a naturally-occurring biomeolecule. It is found in low concentrations in most tissues of the body and functions as a local hormone. As with any local hormone, it is very rapidly metabolized in the tissues of synthesis (half-life estimated to be 3.5 minutes). It is inactivated within the tissues by the enzyme 15-hydroxyprostaglandin dehydrogenase (PGDH). Any PGE2 that escapes local inactivation is rapidly excreted by the kidneys.

**STORAGE :**

The syringe and remaining gel, if any, should be discarded after use.

**PACKAGING AND STORAGE :**

The Gel may be expressed by uterine hypercontractility and uterine hypertonus.

The Gel should be stored in the refrigerator between 2°C to 8°C. Do not freeze.

**PACKAGING :**

- The contents of the syringe should be used on one patient only.
- The syringe and remaining gel, if any, should be discarded after use.
- The Gel should be stored in the refrigerator between 2°C to 8°C. Do not freeze.

**FOR THE USE ONLY OF AN OBSTetrician OR A HOSPITAL OR A LABORATORY**

Dinoprostone Gel

**DESCRIPTION :**

- Each syringe contains 0.5 mg Dinoprostone BP per 3.0 g gel. For Endometrial Application.

**PRECAUTIONS**

- Asthma or History of asthma.
- Cervical stenosis.
- Dizziness.
- Headache.
- Vomiting.
- Vascular insufficiency.
- Hypertension.
- Lung disease.

**INDICATION**

- Induction of labour
- Premature rupture of the membranes
- Cervical ripening
- Fetal distress
- Failed induction of labour

**PHARMACOLOGY :**

Dinoprostone (PGE2) is a naturally occurring biomolecule. It is found in low concentrations in most tissues of the body and functions as a local hormone. As with any local hormone, it is very rapidly metabolized in the tissues of synthesis (half-life estimated to be 3.5 minutes). It is inactivated within the tissues by the enzyme 15-hydroxyprostaglandin dehydrogenase (PGDH). Any PGE2 that escapes local inactivation is rapidly excreted by the kidneys.

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