For the use only of an Obstetrician or a Hospital or a Laboratory

Dinoprostone Gel
PRIMIGYN™ 0.5 mg

DESCRIPTION :
Translucent gel containing 0.5 mg Dinoprostone BP per 3.0 g gel. For Endocervical Application.

COMPOSITION :
Each syringe contains :
Dinoprostone BP ..... 0.5 mg
In a suitable base.

PHARMACOLOGY :
PRIMIGYN™ contains Dinoprostone, the naturally occurring form of prostaglandin E2 (PGE2),

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 (the half-life estimated to be 2.5-5 minutes). **PRIMIGYN™** Gel (Dinoprostone) administered endocervically may stimulate the myometrium of the gravid uterus to contract in a manner similar to contractions seen in the term uterus during labor.

In pregnancy, PGE2 is secreted continuously by the fetal membranes and placenta and plays an important role in the final events leading to the initiation of labor. It is known that PGE2 stimulates the production of PGF2 which in turn sensitizes the myometrium to endogenous or exogenously administrated oxytocin. Dinoprostone is also capable of stimulating smooth muscle of the gastrointestinal tract in humans. This activity may be responsible for the vomiting and / or diarrhea that is occasionally seen when Dinoprostone is used for preinduction cervical ripening.

PGE2 plays an important role in the complex set of biochemical and structural alterations involved in cervical ripening. PGE2 is completely metabolized in humans. PGE2 is extensively metabolized in the lungs,
and the resulting metabolites are further metabolized in the liver and kidney. The major route of elimination of the products of PGE2 metabolism is the kidneys.

INDICATION :
PRIMIGYN™ Gel is indicated for ripening and dilatation of an unfavorable cervix in pregnant women for labour induction.

CONTRAINDICATIONS :
There are no absolute contraindications for the use of **PRIMIGYN™** Gel. However, its use in the following circumstances is not recommended.

1. Patients who are hypersensitive to prostaglandins.
2. Patients in whom oxytocics are generally contraindicated like;
a) Cases with a history of cesarean section or major uterine surgery.
b) Cases in which cephalopelvic disproportion is present.
c) Cases in which there is a history of difficult labor and/or traumatic delivery.
d) Grand multiparae with six or more previous term pregnancies cases with non-vertex presentation.
e) Cases with hyperactive or hypertonic uterine patterns.
f) Cases of fetal distress where delivery is not imminent.
g) In obstetric emergencies where the benefit-to-risk ratio for either the fetus or the mother favors surgical intervention.

3. Situations where vaginal delivery is not indicated as in herpes genitalis and patients with vasa previa, placenta previa or unexplained vaginal bleeding during this pregnancy.

Contraindicated in Early, Mid-trimester Pregnancy and Breast feeding. (Except for Women undergoing an MTP or a therapeutic abortion).

WARNING :
It is found that prostglandins potentiate the action of oxytocin on gravid uterus. When oxytocin is used subsequently for induction of labour, the uterine activity should be carefully monitored.

PRECAUTIONS :
Certain precautions should be exercised in using **PRIMIGYN™** Gel in the following cases :
1. Patients with glaucoma or raised intraocular pressure.
2. Asthma or history of asthma.
3. Pelvic infections.
4. Cardiac disease.
5. Renal impairment.
6. Hepatic impairment.
7. Lung disease.

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

ADVERSE REACTIONS :
No life threatening adverse reactions are reported with the use of **PRIMIGYN™** Gel. Occasional nausea / vomiting or diarrhoea, Vaginal irritations, Abdominal & Back pain, Headache & Dizziness are reported.

Uterine contractile abnormalities with or without foetal distress have also been reported.
Intrapartum foetal bradycardia are reported.

PACKAGING :
PRIMIGYN™ 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 internal os using the catheter which is enclosed. The patient should be instructed to remain recumbent or lying down on one side for at least 30 minutes.

DIRECTION FOR USE :
PRIMIGYNTM Gel is supplied in a specially designed ready to use disposable syringe. The syringe comprises of three main components : (1) The catheter, (2) The plunger, (3) The barrel. When packed, the plunger is attached to the nozzle of the barrel. To administer the drug it is necessary to remove the endstopper & assemble the syringe.

The 3 components :
1) Catheter
2) Plunger
3) Barrel

Unscrew the plunger
from nozzle of the
barrel.

Screw on the catheter,
which is packed
separately on to
the nozzle.

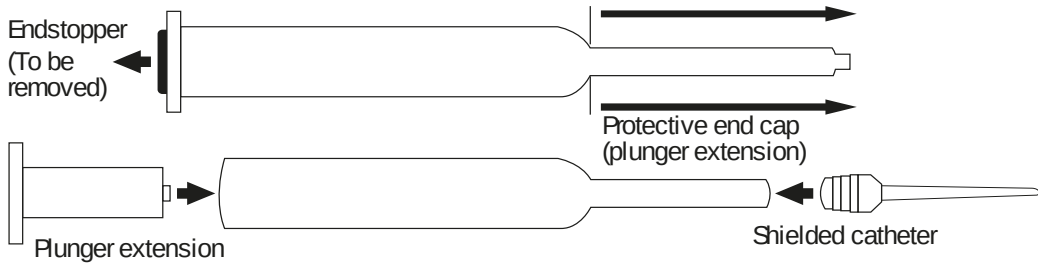
Push the plunger to
expel the gel through
the catheter.

An overage is added to compensate the gel that remains in the catheter.

OVERDOSAGE :
Overdosage with **PRIMIGYN™** Gel may be expressed by uterine hypercontractility and uterine hypertonus. Because of the transient nature of PGE2 -induced myometrial hyperstimulation, nonspecific, conservative management was found to be effective in the vast majority of the cases; ie, maternal position change and administration of oxygen to the mother. β-adrenergic drugs may be used as a treatment of hyperstimulation following the administration of PGE2 for cervical ripening.

STORAGE :
PRIMIGYN™ Gel should be stored in the refrigerator between 2°C to 8°C. Do not freeze.

The contents of the syringe should be used for one patient only.
The syringe and remaining gel, if any, should be discarded after use.



Manufactured by :
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Marketed by :
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