

GLANDIN-E2 Vaginal Gel 2mg (Dinoprostone Eur.P.)

COMPOSITION:

Each 3g (2.5ml) vaginal gel contains:
Dinoprostone (Eur.P.). ... 2mg. [NQ's Specs.]

INDICATIONS: Glandin-E2 Vaginal Gel is indicated for the induction of labour, when there are no fetal or maternal contra-indications.

DOSAGE AND ADMINISTRATION: In primigravida patients with unfavourable induction features (Bishop score of 4 or less), an initial dose of 2mg should be administered vaginally. A second dose of 2mg may be administered after 6 hours. Maximum dose 4mg in unfavourable primigravida patients.

The syringe should be assembled by following the sequence in the diagram. The gel should be inserted high into the posterior fornix avoiding administration into the cervical canal. The patient should be instructed to remain recumbent for at least 30 minutes.

CONTRA-INDICATIONS: Glandin-E2 Vaginal Gel should not be used where the patient is sensitive to prostaglandins.

Glandin-E2 Vaginal Gel is not recommended in the following circumstances:

- 1) For patients in whom oxytocic drugs are generally contra-indicated or where prolonged contractions of the uterus are considered inappropriate such as: Cases with a history of caesarean section or major uterine surgery; Cases where there is cephalopelvic disproportion; Cases in which fetal malpresentation is present; Cases in which there is clinical suspicion or definite evidence of pre-existing fetal distress;
- 2) Patients with ruptured membranes.
- 3) In patients with a past history of/or existing pelvic inflammatory disease, unless adequate prior treatment has been instituted.
- 4) In patients where there is clinical suspicion or definite evidence of placenta praevia or unexplained vaginal bleeding during this pregnancy.
- 5) Patients with active cardiac, pulmonary, renal or hepatic disease.

INTERACTIONS WITH OTHER DRUGS: Since it has been found that prostaglandins potentiate the effect of oxytocin, it is not recommended that these drugs are used together. If used in sequence, the patient's uterine activity should be carefully monitored.

ADVERSE EFFECTS: The most commonly reported events are vomiting, nausea and diarrhoea. Certain rare events that should be especially noted are: Hypersensitivity to the drug; uterine rupture; and cardiac arrest.

Other adverse effects, reported in decreasing order of severity are:

Pulmonary/amniotic fluid embolism;
Abruptio placenta;
Stillbirth, neonatal death;
Uterine hypercontractility or hypertonus;
Fetal distress;
Systemic hypertension (maternal);
Bronchospasm/asthma;
Rapid cervical dilation;
Fever;
Backache;
Rash;

Vaginal symptoms (warmth, irritation, pain).

In addition, other adverse reactions that have been seen with the use of prostaglandin E2 for term labour induction have included: Uterine hypercontractility with fetal bradycardia; uterine hypercontractility without fetal bradycardia; and low Apgar scores in the newborn.

USE IN PREGNANCY AND LACTATION: Glandin-E2 Vaginal Gel is only used during pregnancy, to induce labour. Prostaglandins are excreted in breast milk. This is not expected to be a hazard given the circumstances in which the product is used.

SPECIAL WARNINGS AND PRECAUTIONS: This product should be used only in hospitals and clinics with specialized obstetric units and should only be used where 24 hour resident medical cover is provided. Use the total contents of the syringe for one patient only. Discard after use. Handle this product with caution to prevent contact with skin.

Wash hands thoroughly with soap and water after administration. Caution should be exercised in the administration of prostaglandin E2 in patients with:

- Asthma or a history of asthma;
- Epilepsy or a history of epilepsy;
- Glaucoma or raised intra-ocular pressure;
- Compromised cardiovascular, hepatic or renal function;
- Hypertension.

As with any oxytocic agent, Glandin-E2 Vaginal Gel should be used with caution in patients with compromised (scarred) uteri. In labour induction, cephalopelvic relationships should be carefully evaluated before use of prostaglandin E2. During use, uterine activity, fetal status and the progression of cervical dilation should be carefully monitored to detect possible evidence of undesired responses, e.g. hypertonus, sustained uterine contractions, or fetal distress. In cases where there is a known history of hypertonic uterine contractility or tetanic uterine contractions, it is recommended that uterine activity and the state of the fetus should be continuously monitored throughout labour. The possibility of uterine rupture should be borne in mind where high tone uterine contractions are sustained.

OVERDOSAGE: Uterine hypertonus or unduly severe uterine contractions have rarely been encountered, but might be anticipated to result from overdosage. Where there is evidence of fetal distress or uterine hypertonus, then prompt delivery is indicated. Treatment of overdosage must be, at this time, symptomatic, since clinical studies with prostaglandin antagonists have not progressed to the point where recommendations may be made.

HOW TO ASSEMBLE SYRINGE:

- 1 Remove from packaging.



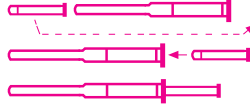
- 2 Remove the plastic plug from end of the syringe.



- 3 Remove the syringe cap from the syringe.



- 4 Insert syringe cap into barrel of syringe.



INSTRUCTIONS:

The contents of syringe are for single use for one patient. Discard the syringe after use. Store in refrigerator (2-8°C). Keep out of the reach of children.

PRESENTATION:

Glandin-E2 Vaginal Gel 2mg is provided in a disposable plastic syringe.

گلیڈن این ای ۲-ویجینائل جیل (ڈائنوپروسٹون) ۲ ملی گرام

اجزاء ترکیب: ۳ گرام گلیڈن این ای ۲-ویجینائل جیل (۲.۵ ملی لیٹر) میں ۲ ملی گرام ڈائنوپروسٹون شامل ہے۔
فوائد: گلیڈن این ای ۲-ویجینائل جیل درد کو پیدا کرنے کیلئے استعمال کی جاتی ہے بشرطیکہ ماہیائے بیچہ میں اس دوا کے خلاف کوئی ممنوع علامات نہ پائی جائیں۔

احتیاط: دوا کے استعمال کے بعد مریض کو تقریباً ۳۰ منٹ تک اسی حالت میں لیٹے رہنے دیں۔ پیک کولے کے بعد دوا فوراً استعمال کریں۔
ہدایات: اس سرنج میں موجود دوا صرف ایک دفعہ استعمال کے لئے ہے۔ استعمال کے بعد سرنج کو ضائع کر دیں۔
۲ سے ۸ ڈگری سینٹی گریڈ فریج میں رکھیں۔ بچوں کی پہنچ سے دور رکھیں۔
طریقہ فراہمی: گلیڈن این ای ۲-ویجینائل جیل ۲ ملی گرام پہلے سے بھری ہوئی سرنج کے تیل پیک ڈبے میں دستیاب ہے۔

Manufactured by:
NABIQASIM INDUSTRIES (PVT.) LTD.
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PHARMA Karachi-Pakistan.

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