

# Preglan-E2 (Dinoprostone) پریگلان۔ ای ۲ (ڈائنوپروسٹون) ڈائنوپروسٹون

3mg Vaginal Tablet

۳ ملی گرام گولی

## COMPOSITION:

Each tablet contains:  
Dinoprostone (U.S.P.) ..... 3 mg  
Product Complies Platinum Specs.

## PHARMACOLOGICAL ACTION:

The exact mode of action of the prostaglandins is not yet completely understood. Preglan-E2 tablet have been shown to have a local action on isolated uterine musculature and clinically its main action is oxytocic. However, unlike other oxytocics, Preglan-E2 tablet exhibit the capacity of the prostaglandins to influence uterine activity at any stage of gestation. Preglan-E2 tablet do not exhibit an antidiuretic effect.

## INDICATIONS:

Preglan-E2 vaginal Tablet are indicated for the induction of labour, especially in patients who are either multiparous or those with favourable induction features.

Clinical safety and efficacy has been demonstrated for labour induction with the following diagnosis:

1. Elective labour disorders.
2. Postmaturity.
3. Hypertensive disorders.
4. Foetal growth retardation.
5. Poor obstetric history.
6. Maternal age greater than 35 years.
7. Rh disease.
8. Placental insufficiency.
9. Clinical/latent diabetes mellitus.

## DOSAGE AND ADMINISTRATION:

One Tablet (3 mg) to be inserted high into the posterior fornix.  
A second tablet may be inserted after 6 - 8 hours if labour is not established. Maximum dose 6 mg. Continuous administration of the drug for more than 2 days is not recommended.

## CONTRAINDICATIONS:

Preglan-E2 Vaginal tablets are not recommended in the following:

1. For patient in whom oxytocic drugs are generally contraindicated or where prolonged contractions of the uterus are considered inappropriate. Such as:  
Cases in which a history of Caesarean Section of major uterine surgery;  
Cases in which major degrees of cephalopelvic disproportion may be Present;  
Cases in which there is a history of difficult labour and/or traumatic delivery;  
Grand multiparae with six or more previous term pregnancies;
2. Patients with ruptured membranes.
3. Patients with known hypersensitivity to prostaglandins.

## WARNINGS AND PRECAUTIONS:

1. Since it has been found that prostaglandins may potentiate the effect of oxytocin, it is recommended that, if these drugs are used together or in sequence, the patient's uterine activity should be carefully monitored.
2. During use, uterine activity foetal 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 foetal 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 foetus should be continuously monitored throughout labour. The possibility of uterine rupture should be borne in mind where high-tone myometrial contraction are sustained.

3. In labour induction foeto-pelvic relationships should be carefully evaluated before the use of Preglan-E2 vaginal tablets.
4. Caution should be exercised in the administration of Preglan-E2 vaginal tablets for the induction of labour in patients with:  
A. Asthma or history of asthma.  
B. Glaucoma or raised intraocular pressure.
5. Animal studies lasting several weeks at high doses have shown that prostaglandins of the E and F series can induce proliferation of bone but there is no evidence that short term administration of prostaglandin E2 can cause similar bone effects.

## SIDE EFFECTS:

Very few adverse reactions have been reported during clinical trials in the evaluation of Preglan-E2 vaginal Tablets for labour induction. Those that have been reported and their frequencies are indicated below:

1. Gastrointestinal (2%): Nausea and vomiting.
2. Uterine hypercontractility with foetal bradycardia (1.0%).
3. Uterine hypercontractility without foetal bradycardia (0.5%).
4. Rapid cervical dilatation with low Apgar score (0.5%).
5. Headache (0.5%).

## PRESENTATION:

Preglan-E2 Vaginal Tablet is presented in pack of 1 tablet.

## INSTRUCTIONS:

Not to be taken orally.  
**Dosage:** As directed by the physician.  
Store in refrigerator between 2 to 8 °C.  
Protect from light & moisture.  
To be dispensed on the prescription of a registered medical practitioner only.  
Keep out of the reach of children.

دوا کھانے کے لئے نہیں ہے۔

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

دوا کو ریفریجریٹر میں ۲ سے ۸ درجہ حرارت کے درمیان میں رکھیں۔

دوا کوئی اور روٹی سے بچا کر رکھیں۔

صرف ریسیڈ ڈاکٹر کے نسخے پر فرہشت کریں۔

بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:

**Platinum**  
Pharmaceuticals (Pvt) Ltd.

A-20, North Western Industrial Zone,  
Bin Qasim, Karachi-75020, Pakistan.

QAR No. AW16-0088

**Platinum**  
Pharmaceuticals (Pvt.) Ltd.

Product : Preglan  
Components: Leaflet  
Country : Local

Dimension: 85 x 145 mm  
Modified Date : 08-09-2016  
Started Date: 08-09-2016  
Concepts by: Nadeem ul Haq  
Design by : Rahil Rahim  
QAR No. AW16-0088  
Supersedes: 060028-2004

COLORS  
Pantone Black C

Department	Marketing	Regulatory	Quality Control	Quality Control Head	Procurement
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Signature					
Date / Time					