SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM

PRANDIN E_2® 1 mg (Vaginal Gel)

PRANDIN E_2® 2 mg (Vaginal Gel)

COMPOSITION

Each unit dose of 3,0 grams (2,5 ml) contains 1,0 mg or 2,0 mg dinoprostone.

CATEGORY AND CLASS

A 19 Oxytocics

PHARMACOLOGICAL ACTION

PGE_2 promotes cervical ripening and stimulates uterine smooth muscle contractions.

INDICATIONS

PRANDIN E_2 Vaginal Gel is indicated for induction of labour in at-term or near-term pregnant patients where there are no foetal or maternal contraindications.

CONTRAINDICATIONS

PRANDIN E_2 Vaginal Gel should not be used in patients known to be hypersensitive to PGE_2 or any other constituents of the gel.

Labour should not be induced in patients who have any of the following findings:

1. Grand multiparity (five or more previous deliveries).
2. Engagement of the head has not taken place.
3. The patient has had previous uterine surgery, e.g. caesarean section, hysterotomy or myomectomy.

4. Cephalopelvic disproportion.
5. Foetal heart rate pattern suggests incipient foetal compromise.
6. Obstetric conditions where either maternal or foetal benefit/risk ratio favours surgical intervention.
7. Unexplained vaginal discharge and/or unexplained uterine or vaginal bleeding during current pregnancy.

WARNINGS AND SPECIAL PRECAUTIONS

1. It is recommended, during labour induction with PGE_2 gel, that continuous electronic monitoring of uterine activity and foetal heart rate be employed.
2. PGE_2 gel for labour induction should be used with caution in patients with compromised cardiovascular, hepatic, or renal function and in patients with asthma.
3. Caution should also be exercised in the administration of oxytocic agents, including PRANDIN E_2 Vaginal Gel, for the induction of labour in patients with multiple gestation.
4. If patients develop uterine hypertonus or hypercontractility or where abnormal foetal heart patterns develop, the clinical situation must be re-evaluated and suitable measures instituted.
5. As with any oxytocic agent, the possibility of uterine rupture should be considered in the presence of excessive uterine activity or unusual uterine pain.
6. Oxytocin and prostaglandin therapy should not be used concomitantly.
7. PRANDIN E_2 Vaginal Gel should be used with caution in patients in whom the chorioamniotic membranes have been ruptured.
8. Patients with glaucoma or raised intraocular pressure.

INTERACTIONS

The response to oxytocin may be accentuated in the presence of exogenous prostaglandin therapy. Concurrent use with other agents is not recommended. The sequential use of

oxytocin following administration of PRANDIN E_2 Vaginal Gel is recommended, with a dosing interval of at least 6 hours.

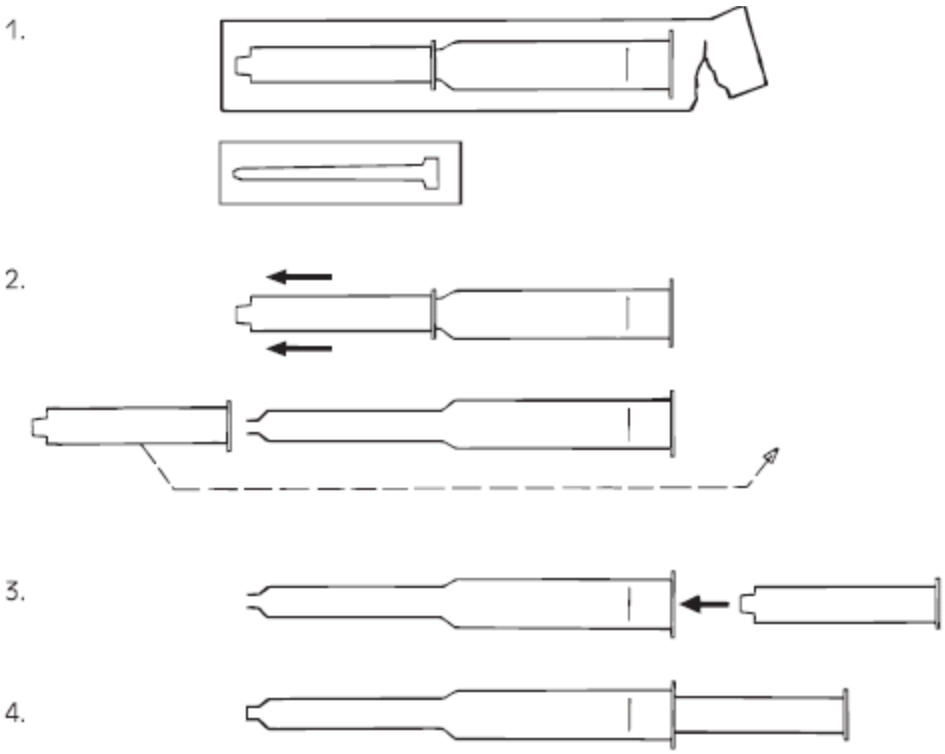
DOSAGE AND DIRECTIONS FOR USE

For labour induction at-/or near-term, the initial dose is 1 mg of PGE_2 gel into the **posterior fornix of the vaginal canal**. After 6 hours, a second dose of either 1 or 2 mg of PRANDIN E_2 Vaginal Gel may be administered depending upon need; i.e. an absence of response to the initial 1 mg dose indicates the 2 mg dose should be given, while a 1 mg dose would be suggested to augment an already present response to the initial dose.

A maximum dose of 3 mg may be used.

Instructions on the method of assembly

1. Remove syringe from blister pack.
2. Remove protective end cap (to serve as plunger extension).
3. Insert protective end cap into syringe.
4. Administer syringe contents.



SIDE EFFECTS

Very Common: ≥ 1/10 (≥ 10%)

Common: ≥ 1/100 and < 1/10 (≥ 1% and < 10%)

Very rare: < 1/10 000 (< 0,01%)

SYSTEM ORGAN CLASS	FREQUENCY	UNDESIRABLE EFFECTS
Investigations:	Very Common	Altered foetal heart rate patterns diagnosed as foetal distress: hyperstimulation
Gastrointestinal disorders:	Common	Nausea, vomiting and diarrhoea
Musculoskeletal and connective tissue disorders:	Common	Back pain
Pregnancy, puerperium and perinatal conditions:	Common	Uterine hypercontractility; Uterine hypertonus
	Very rare	Still birth

R*eproductive system and breast disorders:*	Common	Warm feeling in vagina
General disorders and administration site conditions:	Common	Fever
Immune system disorders:	Very rare	Hypersensitivity reactions
Vascular disorders:	Very rare	Lowered blood pressure

In both laboratory animals and man, large doses of PGE_2 can lower blood pressure, probably as a consequence of its effect on smooth muscle of the vascular system. Transient elevations of body temperature have been observed with doses used for pregnancy termination. PGE_2 is also capable of stimulating the smooth muscle of the gastro-intestinal tract. This property may be responsible for the vomiting and/or diarrhoea that is sometimes associated with the use of PGE_2.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

The principal expressions of an exaggerated response to PRANDIN E_2 Vaginal Gel are either myometrial, hypercontractility or hypertonus. Management of an exaggerated myometrial response should include evacuation of the medication from the vaginal tract, placing the patient in a lateral semi-recumbent position and administration of oxygen. An adrenergic β_2-stimulant may be given intravenously to alleviate the hypertonus.

IDENTIFICATION

A colourless, semi-translucent, viscous gel.

PRESENTATION

PRANDIN E_2 1 mg or 2 mg Vaginal Gel is supplied as a semi-translucent, thixotropic sterile gel as follows:

1 mg or 2 mg PGE_2 per 3 g in syringes for intravaginal application.

STORAGE INSTRUCTIONS

Store in a refrigerator (2 – 8 °C).

Keep out of reach of children.

REGISTRATION NUMBERS

PRANDIN E_2 1 mg Vaginal Gel: W/19/455

PRANDIN E_2 2 mg Vaginal Gel: W/19/456

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Pfizer Laboratories (Pty) Ltd

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

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BOTSWANA: S2

PRANDIN E_2 1 mg - Reg. No.: B9312090

PRANDIN E_2 2 mg - Reg. No.: B9312095

NAMIBIA: S2

PRANDIN E_2 1 mg - Reg. No.: 04/19/0738

PRANDIN E_2 2 mg - Reg. No.: 04/19/0739