

PART III: CONSUMER INFORMATION

PROSTIN® E₂ Vaginal Gel
Dinoprostone vaginal gel
Prostaglandin

This leaflet is part III of a three-part "Product Monograph" published when PROSTIN E₂ Vaginal Gel was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PROSTIN E₂ Vaginal Gel. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

PROSTIN E₂ Vaginal Gel is used to induce labour in pregnant women at the end or near the end of pregnancy.

What it does:

PROSTIN E₂ Vaginal Gel is an oxytocic agent, its effect on uterine smooth muscle leads to cervix ripening (opening of the uterus) and results in labour induction.

When it should not be used:

PROSTIN E₂ Vaginal Gel should not be used if:

- You cannot be given Oxytocic drugs or unable to have prolonged contractions of the uterus;
- You have a ruptured amniotic membranes or choriamnionitis (inflammation of the fetal membranes);
- You have unexplained vaginal bleeding during pregnancy
- You are unable to have vaginal delivery;
- You are allergic to prostaglandins or any oxytocic drug or any of the ingredients in PROSTIN E₂ Vaginal Gel;
- You have no engagement of the baby's head (baby's head down into the pelvic), or abnormal position of the placenta or umbilical cord; or fetal malpresentation (baby in the difficult position for the birth process);
- You have or have had untreated pelvic inflammatory disease;
- You are having heart, lung, kidney or liver disease.

PROSTIN E₂ Vaginal Gel should not be used together with other oxytocics.

What the medicinal ingredient is:

Dinoprostone

What the important nonmedicinal ingredients are:

Colloidal silicon dioxide and triacetin

What dosage forms it comes in:

PROSTIN E₂ Vaginal Gel is semi-translucent viscous gel in a single dose pre-filled-syringe. Each syringe contains 1.0 mg dinoprostone / 2.5 mL or 2.0 mg dinoprostone/2.5 mL.

Each syringe contains:

- 1.0 mg dinoprostone (PGE₂)/2.5 mL Syringe (3 gm)
- 2.0 mg dinoprostone (PGE₂)/2.5 mL Syringe (3 gm)

WARNINGS AND PRECAUTIONS

PROSTIN E₂ Vaginal Gel should be given to you by a doctor experienced in using the drug.

PROSTIN E₂ Vaginal Gel may cause uterine rupture and/or cervical laceration (tearing), and anaphylactoid syndrome of pregnancy (amniotic fluid embolism)

BEFORE you use PROSTIN E₂ Vaginal Gel talk to your doctor if:

- You are 35 years of age and over with complications during pregnancy;
- You have had blood clotting problem after giving birth (post-partum);
- You have or have had seizure;
- You have asthma or glaucoma;
- You have heart, liver, kidney problem.

INTERACTIONS WITH THIS MEDICATION

Before receiving PROSTIN E₂ Vaginal Gel, tell your doctor if you are taking other drugs, including non-prescription and natural health products.

PROPER USE OF THIS MEDICATION

Usual dose:

An initial dose of 1 mg is to be given to you intra vaginally. A dose of 1 mg or 2 mg PROSTIN E₂ Vaginal Gel may be repeated, once, 6 hours later depending upon the response to the initial dose.

You should remain lying down (a lateral or supine position) for 30 minutes after the drug was given to prevent leakage of the gel.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

N/A

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- Possible side effects on mother: strong uterine contractions, failed induction, failure to progress, diarrhea, nausea, vomiting, fever, severe allergic reaction (anaphylactic reaction, anaphylactic shock, anaphylactoid reaction), back pain, uterine rupture, abnormal uterine contraction, warm feeling in vagina, cardiac arrest.
- Possible side effects on baby: abnormal heart rate, distress (unwell), still birth.
- Serious side effect reported with the use of PROSTIN E₂ Vaginal Gel: blood clots inside the blood vessels throughout the body (disseminated intravascular coagulation).

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Abnormal labour affecting fetus		√	
	Fetal distress syndrome		√	
	Increased uterine contractions		√	

This is not a complete list of side effects. For any unexpected effects while taking PROSTIN E₂ Vaginal Gel, contact your doctor or pharmacist.

HOW TO STORE IT

Store in a refrigerator at 2-8°C

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.pfizer.ca> or by contacting the distributor Paladin Labs Inc. at 1-888-867-7426 (Medical Information)

This leaflet was prepared by Pfizer Canada Inc.

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