PART III: CONSUMER INFORMATION

PROSTIN® E_2 Tablets
Dinoprostone
Prostaglandin

This leaflet is part III of a three-part "Product Monograph" published when PROSTIN® E_2 Tablets 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® E_2Tablets. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
PROSTIN® E_2 Tablets is used to induce labour in pregnant women at the end or near the end of pregnancy.

What it does:
PROSTIN® E2 Tablets is an oxytocic agent, it effect on uterine smooth muscle leads to the cervix ripening (opening of the uterus) and results in labour induction.

When it should not be used:
PROSTIN® E2 Tablets should not be used if:

- You cannot be given Oxytocic drugs or unable to have prolonged contractions of the uterus;
- You have unexplained vaginal bleeding during pregnancy;
- You are unable to have vaginal delivery;
- When drugs used to stimulate labour are not required or when prolonged contraction of the uterus may be harmful to the baby's safety or stability of the uterus;
- You are allergic to prostaglandins or any of the other ingredients in the PROSTINE E2 tablets;
- You have no engagement of the baby 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 Tablet should not be used together with other oxytocics

What the medicinal ingredient is:
Dinoprostone

What the important nonmedicinal ingredients are:
Corn starch, colloidal silicon dioxide, lactose anhydrous, magnesium stearate powder; food grade, microcrystalline cellulose.

What dosage forms it comes in:

PROSTIN® E2 Tablets are in glass bottles containing 10 tablets each.

WARNINGS AND PRECAUTIONS

PROSTIN® E2 Tablets should be given to you only by doctor experienced in using the drug.

BEFORE you use PROSTIN® E_2 Tablets talk to your doctor if:

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

INTERACTIONS WITH THIS MEDICATION

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

PROPER USE OF THIS MEDICATION

Usual dose:
The recommended dose of PROSTIN® E2 Tablets is 0.5 mg (one tablet) followed in one hour by a second dose of 0.5 mg (one tablet). All subsequent doses should be given hourly. The lowest effective dose should be used. All doses should be taken with a small amount of water.

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

In studies the most commonly reported adverse reactions were vomiting, with or without nausea and diarrhea (21% at dose 0.5 – 3.0 mg).

Other adverse reactions include Fetal heart changes (6.5%), uterine hypertonus (3.1%), and fetal distress syndrome.

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		√	
	Uerine hypertonus		√	
Uncommon	**Nausea, vomiting, diarrhea**		√	√

This is not a complete list of side effects. For any unexpected effects while taking PROSTIN® E_2 Tablets, contact your doctor or pharmacist.

HOW TO STORE IT

PROSTIN E2 tablets should always be stored under normal refrigeration (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 0701E
  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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