

PART III: CONSUMER INFORMATION

PREPIDIL Gel dinoprostone gel

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

ABOUT THIS MEDICATION

What the medication is used for:

PREPIDIL gel is used to start the "cervical softening" and dilation of the cervix in pregnant women at the end of pregnancy.

What it does:

PREPIDIL gel is an oxytocic agent, its effect on uterine smooth muscle leads to the cervix ripening (opening of the uterus) and results in labor induction.

When it should not be used:

PREPIDIL gel should not be used if:

- You cannot be given Oxytocic drugs or unable to have prolonged contractions of the uterus;
- You have ruptured amniotic membranes or choriomnionitis (inflammation of the fetal membranes)
- You have unexplained vaginal bleeding during pregnancy;
- You are unable to have vaginal delivery;
- When drugs used to stimulate labor 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 other oxytocic drug or any of the other ingredients in PREPIDIL Gel;
- You have no engagement of the baby head (baby's head down into the pelvis), 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; PREPIDIL gel should not be used together with other oxytocics.

What the medicinal ingredient is:

Dinoprostone (PGE₂)

What the important nonmedicinal ingredients are:

Colloidal silicon, dioxide and triacetin

What dosage forms it comes in:

PREPIDIL is supplied as a translucent sterile gel preparation in a prefilled syringe with an accompanying catheter.

Each syringe contains:

0.5 mg dinoprostone (PGE₂)/2.5 mL Syringe (3 g)

WARNINGS AND PRECAUTIONS

PREPIDIL should be given to you by doctor experienced in using this drug.

PREPIDIL gel may cause uterine rupture and/or cervical laceration (tearing), and anaphylactoid syndrome of Pregnancy (amniotic fluid embolism).

BEFORE you use PREPIDIL 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 PREPIDIL gel, tell your doctor if you are taking other drugs, including non-prescription and natural health products.

PROPER USE OF THIS MEDICATION

Usual dose:

The recommended dose of PREPIDIL (dinoprostone gel) is 0.5 mg equivalent to the use of one prefilled syringe. Each syringe is intended for single dose administration.

After you doctor has placed the gel, you should remain lying on your back for 10-15 minutes to minimize gel leakage.

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 (10%), including uterine contractile abnormalities without fetal heart change (5%),

vomiting and diarrhea (5%), fever (>1%), back pain (>1%), warm feeling in vagina (>1%).

Possible side effects on baby (16%), including fetal heart rate change and unclassified fetal distress (13%), uterine contractile abnormalities with fetal heart change (3%), and depressed neonates (13 % at 1 minute):

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 labor affecting fetus		✓	
	Fetal distress syndrome		✓	
	Uterine hypertonus		✓	
Uncommon	Nausea, vomiting, diarrhea		✓	✓

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

HOW TO STORE IT

Store in a refrigerator at a temperature lower than 4°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 Pharma Inc., at 1-888-867-7426 (Medical Information)

This leaflet was prepared by Pfizer Canada ULC.

Last revised: September 5, 2012

(L3: June 30, 2015)

(L3: 06 March, 2025)