



HELP TO RIPEN THE CERVIX IS AT YOUR FINGERTIPS

- A single dose, retrievable dinoprostone with the only vaginal delivery system featuring a polyester retrieval device^{1*}
- CERVIDIL's retrieval system ensures easy and reliable removal of the insert¹

CERVIDIL (dinoprostone) is indicated for the initiation and/or continuation of cervical ripening in patients at or near term in whom there is a medical or obstetrical indication for the induction of labour.¹

* Comparable clinical significance has not been established.

PROPER ADMINISTRATION WILL HELP OPTIMIZE DRUG DELIVERY¹

PREPARE

- Hold CERVIDIL® between 2 fingers and lightly coat with water miscible lubricant.

INSERT

- Gently place your fingers with the insert into the vagina. Position CERVIDIL® transversely in the posterior vaginal fornix being careful not to dislodge the insert when removing fingers. Slightly tuck the retrieval tape into the vagina.

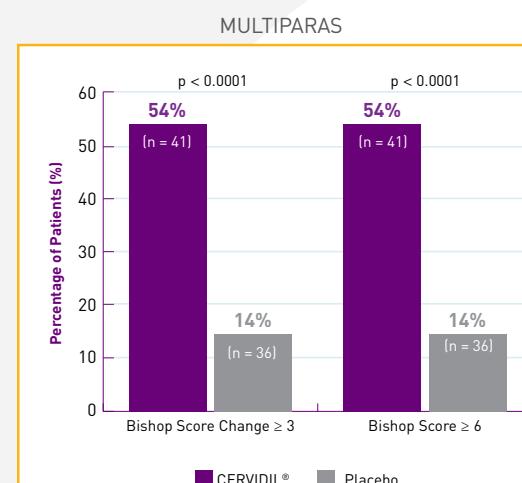
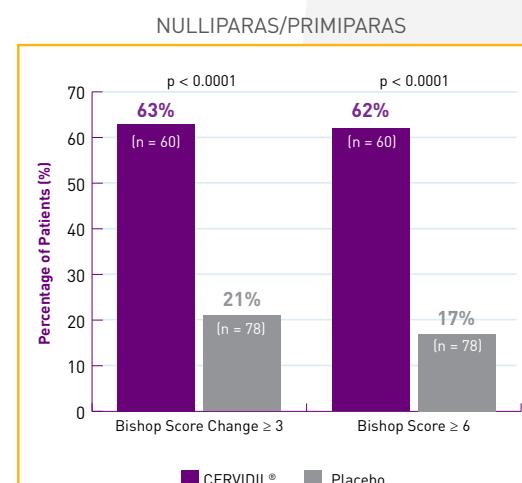
Patients should remain in supine position for 2 hours following insertion but may be ambulatory after. Please see the Product Monograph for complete dosage and administration information.

RETRIEVE

- To retrieve, pull gently on the retrieval tape until the product is fully removed.

Use of oxytocin can be initiated 30 minutes after the removal of the controlled release dinoprostone vaginal insert

CERVIDIL® SHOWED STATISTICALLY SIGNIFICANT CERVICAL RIPENING AFTER 12 HOURS^{2*†‡§}



Study 101-003

Adapted from Rayburn WF, et al.²

CERVICAL RIPENING AT YOUR FINGERTIPS¹

- Each insert contains 10 mg dinoprostone (PGE₂) dispersed throughout its matrix, and releases approx. 0.3 mg/hour PGE₂ over a 12 hour period to maintain constant release.¹
- A dosing interval of at least 30 minutes is recommended for the sequential use of oxytocin following the removal of the dinoprostone vaginal insert.¹

CERVIDIL® is generally well tolerated¹

Adverse events seen in <1.0% of patients¹

Drug related fever	Nausea	Vomiting
Diarrhea	Abdominal pain	

Hyperstimulation was reversed within 2 to 13 minutes of removing CERVIDIL®, in a clinical trial^{1*}

Helps STOP the release of dinoprostone quickly with rapid retrieval system^{1††}

Total drug related adverse events in placebo-controlled trials¹

	Controlled-Studies ¹ Cervidil (n = 320)	Placebo (n = 338)	Study 101-801** Cervidil (n=102)	Placebo (n = 104)
Uterine hyperstimulation w/ fetal distress	2.8%	0.3%	2.9% ^{††}	0%
Uterine hyperstimulation w/out fetal distress	4.7%	0%	2.0% ^{††}	0%
Fetal distress without uterine hyperstimulation	3.8%	1.2%	2.9%	1.0%

* A randomized, double-blind study of 215 patients scheduled to undergo labour induction designed to evaluate the efficacy and safety of CERVIDIL®. All patients had an entry Bishop score of 4 or less and gestational age of 37 or more weeks. During the 12-hour observation period, clinical endpoints included changes in Bishop cervical score and onset of labor.

† Median Bishop score at baseline: Nulliparas patients – CERVIDIL®=2.0; Placebo=2.0; Multiparas patients – CERVIDIL®=3.0 & Placebo=3.0.

‡ Measurable effect was defined as an increase in Bishop score of 3 or more points above baseline or an absolute score of 6 or higher.

§ Treatment success was considered a change in Bishop score after 12 hours (treatment failure was defined as no change in Bishop score after 12 hours).

¶ Controlled Studies (with and without retrieval system).

** Controlled Study (with retrieval system).

†† Out of 102 patients five (4.9%) had hyperstimulation; (2.9%) of the cases were associated with fetal distress; Uterine hyperstimulation reversed within 2–3 minutes after insert retrieval.

†† The retrieval system consists of a one-piece knitted polyester pouch and withdrawal tape. This ensures easy and reliable removal of the insert when the patient's requirement for PGE2 has been fulfilled or an obstetric event makes it necessary to stop further drug administration.

YOUR PESSARY FOR CERVICAL RIPENING



Cervical ripening at your fingertips¹

- The first and only dinoprostone vaginal insert for the induction of cervical ripening^{1*}
- Dinoprostone - an effective molecule for initiation and/or continuation of cervical ripening¹
- The retrieval system ensures easy and reliable removal of the insert¹
- CERVIDIL® is generally well tolerated with a low incidence of adverse events¹

IMPORTANT:

- CERVIDIL® must be kept frozen until use. There is no need for previous warming of the product
- Insert immediately after removal from its foil package

Helps STOP the release of dinoprostone quickly with rapid retrieval system¹

Indication and clinical use:

CERVIDIL® (dinoprostone) is indicated for: Initiation and/or continuation of cervical ripening in patients at or near term in whom there is a medical or obstetrical indication for the induction of labour.

CERVIDIL® is not recommended in the geriatric and pediatric populations.

Contraindications:

- Patients in whom there is clinical suspicion or definite evidence of fetal distress where delivery is not imminent
- Patients with placenta previa or unexplained vaginal bleeding during this pregnancy
- Patients in whom there is evidence or strong suspicion of marked cephalopelvic disproportion
- Patients in whom oxytocic drugs are contraindicated or when prolonged contraction of the uterus may be detrimental to fetal safety or uterine integrity (previous caesarean section or major uterine surgery)
- Multipara with 6 or more previous term pregnancies
- Patients with a history of difficult labour and/or traumatic delivery
- Patients with overdistension of uterus (multiple pregnancy, polyhydramnios)
- Patients with fetal malpresentation
- Patients with a history of epilepsy whose seizures are poorly controlled
- Should not be used simultaneously with other oxytocics
- Should not be used when there is a history of, or current pelvic inflammatory disease, unless adequate prior treatment has been instituted

References:

1. CERVIDIL® Product Monograph. Ferring Inc. September 29, 2006.
2. Rayburn WF *et al.* An intravaginal controlled-release prostaglandin E2 pessary for cervical ripening and initiation of labor at term. *Obstet Gynecol* 1992;79:374-379.

Most serious warnings and precautions:

For Hospital Use Only: CERVIDIL® should be administered only by trained obstetrical personnel in a hospital setting with appropriate obstetrical care facilities. Other relevant warnings and precautions:

- Removal prior to oxytocin administration
- Removal if uterine hyperstimulation is encountered or if labour commences; prior to amniotomy; if there is fetal distress; if there is evidence of maternal or fetal adverse reactions
- Caution in patients with a history of previous uterine hypertonicity, glaucoma, or childhood asthma
- Caution in patients at risk for developing disseminated intravascular coagulation
- Evaluation of cephalopelvic relationships
- Caution in patients with severe renal disease and/or severe hepatic disease accompanied by metabolic aberrations
- Not indicated for use during early or other phases of pregnancy or during lactation
- Monitoring: After insertion, the patient should remain supine and monitored for 2 hours for any evidence of uterine hyperstimulation, change in fetal heart rate or maternal blood pressure or heart rate

For more information:

Please consult product monograph https://pdf.hres.ca/dpd_pm/00002793.PDF important information relating to adverse reactions, drug interactions and dosing information which have not been discussed in this piece.

The Product Monograph is also available by calling 1-866-384-1314.