ADMINISTRATION GUIDE

Cervical ripening with

CONTROL AT HAND

CERVIDIL is easy to insert and remove.[1]

INDICATION

CERVIDIL Vaginal Insert (dinoprostone, 10 mg) 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 labor.

CERVIDIL is designed to be released at approximately 0.3 mg/hour over a 12-hour period. CERVIDIL should be removed upon onset of active labor or 12 hours after insertion.

Upon removal of CERVIDIL, it is essential to ensure that the slab has been removed as it may have separated from the knitted polyester retrieval system and will continue delivering the active ingredient.

IMPORTANT SAFETY INFORMATION

Contraindications

CERVIDIL is contraindicated in:

- Patients with known hypersensitivity to prostaglandins
- Patients in whom there is a clinical suspicion or definitive evidence of fetal distress where delivery is not imminent
- Patients with 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, such as previous cesarean section or uterine surgery (given the potential risk for uterine rupture and associated obstetrical complications, including the need for hysterectomy and the occurrence of fetal or neonatal death)
- Patients already receiving intravenous oxytocic drugs
- Multipara with 6 or more previous term pregnancies

Please see continued Important Safety Information on reverse.
Please see full Prescribing Information in pocket.

Cervidil®
DINOPROSTONE 10mg
VAGINAL INSERT

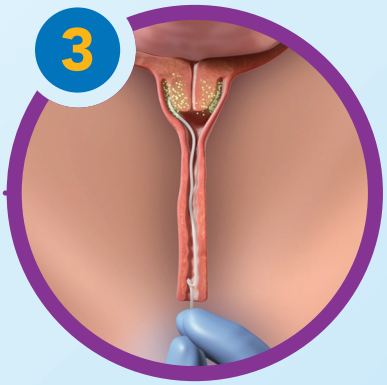
PROPER ADMINISTRATION OPTIMAL DRUG DELIVERY[1]

PREPARE

Pick up the insert between 2 fingers and lightly coat with water-miscible lubricant.

INSERT

Gently place your fingers with the insert into the vagina. Position the insert transversely in the posterior vaginal fornix. Take care not to dislodge the insert when removing fingers. Slightly tuck the retrieval tape into the vagina.



RETRIEVE

To retrieve, locate the retrieval tape and pull it gently, until the product is fully removed.

Upon removal of CERVIDIL, it is essential to ensure that the slab has been removed, as it will continue delivering the active ingredient. This is accomplished by visualizing the knitted polyester retrieval system and confirming that it contains the slab. In the rare instance that the slab is not contained within the polyester retrieval system, a vaginal exam should be performed to remove the slab.

IMPORTANT SAFETY INFORMATION

Contraindications

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WILL HELP

IMPORTANT GUIDELINES

- 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
- CERVIDIL does not require sterile conditions
- The vaginal insert must not be used without its retrieval system
- Do not wrap insert in its retrieval tape
- Do not overlubricate; excess lubricant could prevent optimal swelling and release of dinoprostone from the vaginal insert
- Patients should remain in the recumbent position for 2 hours following insertion, but thereafter may be ambulatory
- CERVIDIL should be removed upon onset of active labor or 12 hours after insertion
- With any evidence of uterine hyperstimulation, sustained uterine contractions, fetal distress, or other fetal or maternal adverse reactions, the vaginal insert should be removed
- CERVIDIL must be removed before oxytocin administration is initiated and the patient's uterine activity carefully monitored for uterine hyperstimulation
- CERVIDIL should also be removed prior to amniotomy and prior to oxytocin administration

Warnings and Precautions

- CERVIDIL is for hospital use only and should be administered only by trained obstetrical personnel in a hospital setting with appropriate obstetrical care facilities.
- Use of dinoprostone may result in inadvertent disruption and subsequent embolization of antigenic tissue causing, in rare circumstances, the development of Anaphylactoid Syndrome of Pregnancy (Amniotic Fluid Embolism).
- Prostaglandins, including CERVIDIL, may augment the activity of oxytocic agents and their concomitant use is not recommended. CERVIDIL must be removed before oxytocin administration is initiated and a dosing interval of at least 30 minutes is recommended for the sequential use of oxytocin.

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Cervidil®
DINOPROSTONE 10mg
VAGINAL INSERT

- **THE ONLY FDA-APPROVED INSERT FOR CERVICAL RIPENING[2]**
- **SINGLE-DOSE CONTROLLED RELEASE OF DINOPROSTONE OVER 12 HOURS[1]**
- **DESIGNED FOR EASY INSERTION AND QUICK REMOVAL[1]**

See the administration video at cervidil.com/administration

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- Uterine activity, fetal status, and the progression of cervical dilatation and effacement should be carefully monitored whenever the CERVIDIL vaginal insert is in place. With any evidence of uterine hyperstimulation, sustained uterine contractions, fetal distress, or other fetal or maternal adverse reactions, the vaginal insert should be removed. CERVIDIL should also be removed prior to amniotomy.
- Caution should be exercised in the administration of CERVIDIL for cervical ripening in patients with ruptured membranes, in cases of non-vertex or non-singleton presentation, and in patients with a history of previous uterine hypertony, glaucoma, or a history of childhood asthma, even though there have been no asthma attacks in adulthood.
- Long-term carcinogenicity and fertility studies have not been conducted with CERVIDIL. No evidence of mutagenicity has been observed with prostaglandin E_2 in the Unscheduled DNA Synthesis Assay, the Micronucleus Test, or Ames Assay.
- Prostaglandin E_2 has produced an increase in skeletal anomalies in rats and rabbits. No effect would be expected clinically, when used as indicated, since CERVIDIL is administered after the period of organogenesis. Prostaglandin E_2 has been shown to be embryotoxic in rats and rabbits, and any dose that produces sustained increased uterine tone could put the embryo or fetus at risk.
- The safety and efficacy of CERVIDIL has been established in women of a reproductive age and women who are pregnant. Although safety and efficacy has not been established in pediatric patients, safety and efficacy are expected to be the same for adolescents.
- Women aged 30 years or older, those with complications during pregnancy and those with a gestational age over 40 weeks have been shown to have an increased risk of postpartum disseminated intravascular coagulation. In addition, these factors may further increase the risk associated with labor induction. In these women, use of dinoprostone should be undertaken with caution. Measures should be applied to detect as soon as possible an evolving fibrinolysis in the immediate postpartum period. An increased risk of postpartum disseminated intravascular coagulation has been described in patients whose labor was induced by physiologic means, either with dinoprostone or oxytocin.

Adverse Reactions

- In clinical trials, the most commonly occurring adverse reactions were uterine hyperstimulation with fetal distress (2.8% vs 0.3% for placebo), uterine hyperstimulation without fetal distress (4.7% vs 0%), and fetal distress without uterine hyperstimulation (3.8% vs 1.2%).
- Drug-related fever, nausea, vomiting, diarrhea, and abdominal pain were noted in less than 1% of patients who received CERVIDIL.

References: 1. Cervidil [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc. **2.** FDA Orange Book. http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm. Accessed August 17, 2015.

Please see additional Important Safety Information inside and full Prescribing Information in pocket.

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