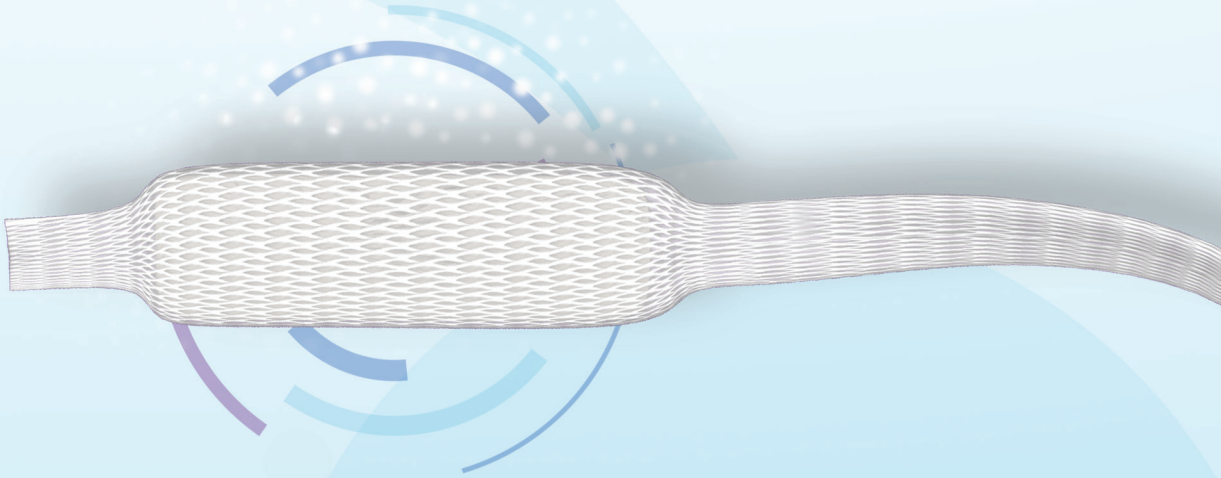
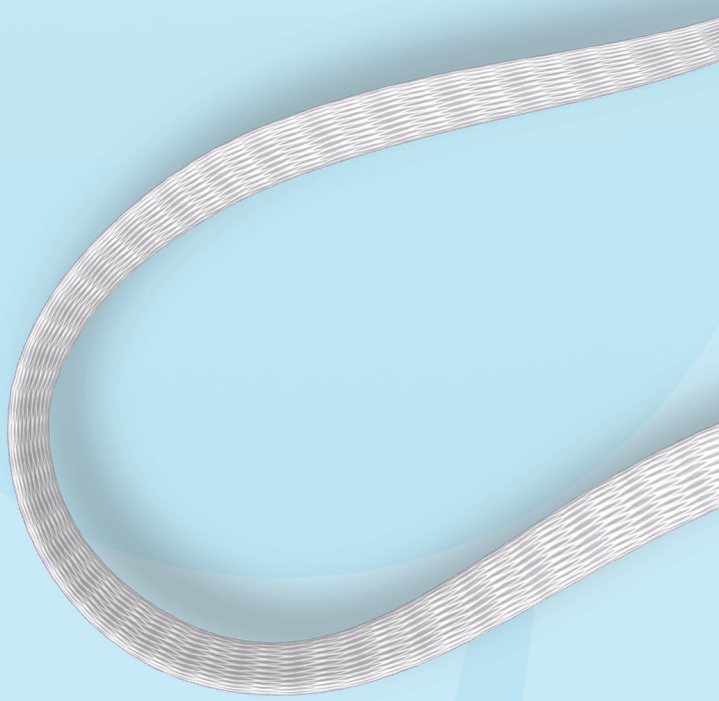


Cervidil®
DINOPROSTONE 10mg
VAGINAL INSERT

ADMINISTRATION GUIDE

Your guide for getting the most out of every CERVIDIL insert



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.

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

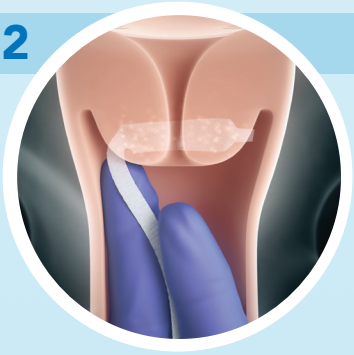
Right Place
Right Time

Proper administration may help increase efficacy

1 PREPARE

- Pick up the insert between 2 fingers, positioning the slab end to be inserted first, and extend the tape
- Apply a minimal amount of water-miscible lubricant to 2 fingers (not to the slab itself)

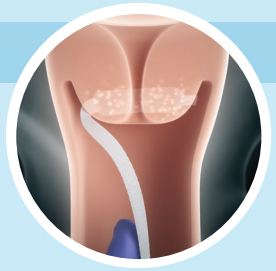
2 INSERT



- Gently place your 2 fingers with the insert into the vagina
- **Position the insert transversely in the posterior vaginal fornix[1]**

Right Place

3 SECURE



- Slightly tuck the retrieval tape just inside the vagina, leaving a small portion of the tail outside of the vagina
- Patients should remain in the recumbent position for 2 hours following insertion but thereafter may be ambulatory[1]

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)

Important guidelines[1]

Prior to inserting CERVIDIL:

- CERVIDIL should be administered only by trained obstetrical personnel in a hospital setting with appropriate obstetrical care facilities
- CERVIDIL must be kept frozen until use and is stable when stored in a freezer for a period of 3 years
- There is no need for previous warming of the product
- Insert immediately after removal from its foil package
- CERVIDIL should not be used without its retrieval system
- CERVIDIL does not require sterile conditions

CERVIDIL should be removed:

- 12 hours after insertion or upon onset of active labor
- Prior to amniotomy
- With any evidence of uterine hyperstimulation, sustained uterine contractions, fetal distress, or other fetal or maternal adverse reactions
- Before oxytocin administration is initiated; the patient's uterine activity should be carefully monitored for uterine hyperstimulation

Warnings and Precautions (continued)

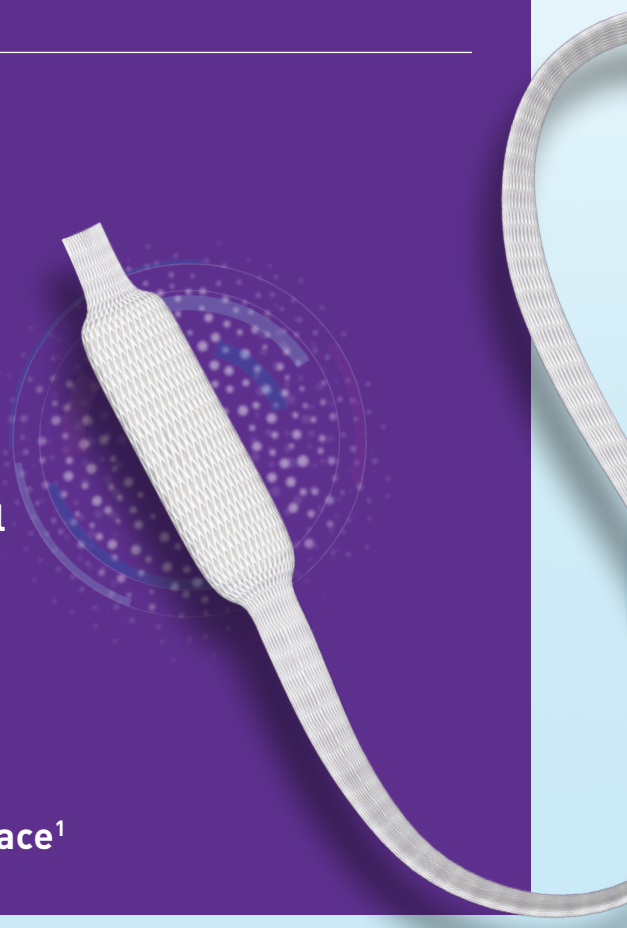
- Prostaglandin E_2 has produced an increase in skeletal anomalies in rats and rabbits. No effect would be expected clinically, when used as indicated, since CERVIDIL is administered after the period of organogenesis. Prostaglandin E_2 has been shown to be embryotoxic in rats and rabbits, and any dose 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.

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

Cervidil®
DINOPROSTONE 10mg
VAGINAL INSERT

Administration tips from healthcare professionals

- **Never open the CERVIDIL insert package with scissors or other sharp objects[1]**
- **Do not wrap the tape around the insert or cut the tape from the slab**
- **Use a pillow or bedpan to elevate the pelvic bone when placing CERVIDIL**
- **Avoid excess lubricant; it could prevent optimal swelling and release of dinoprostone from the vaginal insert[1]**
- **Expecting mothers can begin to move around 2 hours after CERVIDIL is inserted, but when ambulatory or when using the bathroom, care should be taken to ensure the insert stays in place[1]**



Right Time

Let CERVIDIL do its job

- CERVIDIL delivers a controlled release of dinoprostone for up to 12 hours[1]
- Each patient is unique and may respond differently to treatment

Contraindications (continued)

- Patients already receiving intravenous oxytocic drugs
- Multipara with 6 or more previous term pregnancies

Warnings and Precautions

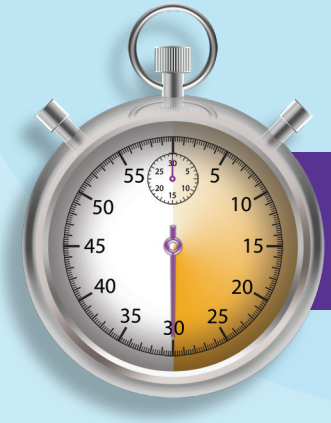
- CERVIDIL is for hospital use only and should be administered only by trained obstetrical personnel in a hospital setting with appropriate obstetrical care facilities.
- Use of dinoprostone may result in inadvertent disruption and subsequent embolization of antigenic tissue causing, in rare circumstances, 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.

Easy to remove when it's time

RETRIEVE

- Do a cervical exam and check the contraction pattern before removing
- To remove the CERVIDIL insert, locate the retrieval tape from inside the vagina and pull on it gently until it is fully removed
- Inspect the insert to be sure the slab has been removed, as it will continue delivering the active ingredient. Visualize the knitted polyester retrieval system and confirm that it contains the slab[1]*

*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.[1]



Once CERVIDIL is removed, Pitocin® (oxytocin) can be administered after 30 minutes.[1]

Warnings and Precautions (continued)

- 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.

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

Cervidil®
DINOPROSTONE 10mg
VAGINAL INSERT

Get the most out of CERVIDIL

Right Place Right Time

By following proper administration, you and your hospital can help ensure that CERVIDIL works to its full potential.

- Each CERVIDIL insert provides a controlled release of dinoprostone at 0.3 mg/hour for up to a period of 12 hours[1]
- CERVIDIL is well-tolerated, with a low incidence of adverse events in clinical trials[1]
  - Drug-related fever, nausea, vomiting, diarrhea, and abdominal pain were noted in less than 1% of patients who received CERVIDIL
- CERVIDIL can be administered by L&D nurses

Visit CervidilTraining.com to watch the administration video and to request a live in-service training session.

Reference: 1. CERVIDIL [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.

Warnings and Precautions (continued)

- 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.

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

Cervidil® DINOPROSTONE 10mg VAGINAL INSERT