

INDICATION

CERVIDIL® (dinoprostone, 10 mg) is a vaginal insert approved to start and/or continue the ripening of the cervix in pregnant women who are at or near the time of delivery and in whom there is a medical reason for inducing (bringing on) labor.

For the first two (2) hours following insertion, you should remain lying down. If you sit up or walk after the first two hours, you should be careful to ensure the insert remains in place. While CERVIDIL is inserted, your doctor will carefully monitor your progress and your baby's well-being and will determine when the insert should be removed.

IMPORTANT SAFETY INFORMATION

CERVIDIL should only be inserted by a trained healthcare professional in a hospital setting appropriate for childbirth.

Please see Important Safety Information throughout and enclosed full Prescribing Information.



IMPORTANT SAFETY INFORMATION

Who should NOT be given CERVIDIL?

You should NOT be given CERVIDIL if you have:

- Experienced an allergic reaction to prostaglandins (certain hormone-like substances)
- Experienced unexplained vaginal bleeding during your pregnancy
- Already started receiving drugs to induce labor
- Given birth six or more times in your lifetime

Who should NOT be given CERVIDIL? (cont)

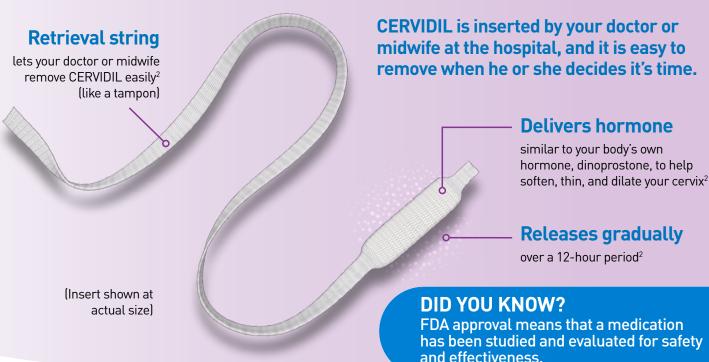
You should also NOT be given CERVIDIL if your doctor has determined that:

- Your baby is in distress and needs to be delivered urgently
- Your baby's head or body may be too large to fit through your pelvis ("cephalopelvic disproportion")
- Drugs used to induce labor are not appropriate for you or that prolonged contraction of your uterus may be harmful to you or your baby such as if you have had a previous cesarean section or surgery on your uterus.



The ONLY FDA-approved get your cervix ready for

vaginal insert designed to labor^{2,3}



IMPORTANT SAFETY INFORMATION

What are the most serious risks associated with the use of CERVIDIL?

The induction of labor has been associated with an increased risk of a disorder of abnormal clotting of the blood that results in excessive bleeding immediately after birth ("disseminated intravascular coagulation" or DIC). The risk is higher in women over age 30, those with complications during pregnancy, and those whose pregnancy has lasted longer than 40 weeks.

What are the most serious risks associated with the use of CERVIDIL? (cont)

In rare cases, the use of CERVIDIL has been associated with an increased risk of a life-threatening event to the mother called "amniotic fluid embolism." The cause of amniotic fluid embolism is not well understood but it is believed that some amniotic fluid or other substances can get into your bloodstream and start a severe reaction that can cause heart and lung collapse.

Common questions

Why do I need CERVIDIL?

Your doctor or midwife may decide it's time to use CERVIDIL because you are at, or past, your due date; your water breaks but your body hasn't started labor yet; or there is medical need for your baby to be delivered.²

Why does my cervix need to get ready for labor?

When the cervix is soft, thin, and dilated, the baby can then pass through your birth canal. CERVIDIL is the only FDA-approved vaginal insert to help get your cervix ready for labor.^{2,3}

Why can't my cervix get ready on its own?

Sometimes your body needs more dinoprostone, a hormone that gets the body ready for labor. Your doctor or midwife can decide if help from CERVIDIL is needed.



IMPORTANT SAFETY INFORMATION

What should I discuss with my doctor before labor induction begins or CERVIDIL is given?

As you would throughout your pregnancy, be sure to tell your doctor about all prescription or over-the-counter medications you are taking. Before CERVIDIL is given, be sure you have told your doctor about all your current and past medical conditions, including:

- If your water has broken
- Any unexplained vaginal bleeding during pregnancy
- All uterine surgeries, especially previous cesarean section or uterine surgery
- A history of contractions lasting more than 2 minutes
- Glaucoma
- Asthma, even if you had childhood asthma and have had no asthma attacks as an adult

What are the most common side effects of CERVIDIL?

The most common side effects associated with the administration of CERVIDIL are contractions occurring at a rate faster than normal (tachysystole) and signs that the baby is exhausted or in distress (uterine hyperstimulation). In clinical trials, these effects occurred alone or together in less than 1 in 20 women who were given CERVIDIL.

In clinical trials, fever, nausea, vomiting, diarrhea and abdominal pain were noted in less than 1 in 100 women who were given CERVIDIL.

This is not a complete list of possible side effects.



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Common questions

How does CERVIDIL work?

CERVIDIL is designed to work directly on your cervix to help make it soft, thin, and dilated. When your doctor or midwife decides it's time, he or she can quickly remove CERVIDIL using the long retrieval string² (like a tampon).

Does CERVIDIL cause contractions?

CERVIDIL is used for preparing the cervix for labor and may start mild contractions during the cervical ripening process. Some patients may require Pitocin® or oxytocin to either start or strengthen contractions.

Is CERVIDIL the same as Pitocin or oxytocin?

No, CERVIDIL is used to help get your cervix ready, which is needed before starting contractions. Pitocin or oxytocin is used to generate or strengthen existing contractions.

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In rare cases, the use of CERVIDIL has been associated with an increased risk of a life-threatening event to the mother called "amniotic fluid embolism." The cause of amniotic fluid embolism is not well understood but it is believed that some amniotic fluid or other substances can get into your bloodstream and start a severe reaction that can cause heart and lung collapse.

CERVIDIL is inserted by your doctor or midwife at the hospital, and it is easy to remove when he or she decides it's time.

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References: 1. Osterman MJK, Martin JA. Recent declines in induction of labor by gestational age. NCHS data brief, no 155. Hyattsville, MD: National Center for Health Statistics. 2014. 2. Cervidil [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc. 3. FDA Orange Book. http://www.acceessdata.fda.gov/scripts/cder/ob/docs/tempai. cfm. Accessed August 17, 2015. 4. Data on file. Ferring Pharmaceuticals Inc. 5. Food and Drug Administration. Drugs at FDA http://www.accessdata.fda.gov/scripts/cder/drugsatfda.Accessed March 17, 2016.



Feel confident in **CERVIDIL**

- The ONLY FDA-approved vaginal insert^{2,3}
- Specifically designed for cervical ripening
- Easily² removed when your doctor or midwife decides it's time

Getting your cervix ready with CERVIDIL can be the first step to meeting your baby. Learn more at cervidilinfo.com

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