CERVIDIL®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or midwife.

1. Why am I being given CERVIDIL?

CERVIDIL can be used to prepare the birth canal in women who require, and have favourable features for, induction of labour after 37 weeks of pregnancy have been completed. It helps the part of the birth canal, known as the cervix, to soften and open to allow the baby through. It contains the active ingredient dinoprostone.
There can be several reasons why you might need treatment with CERVIDIL. Ask your doctor if you would like to know more.
For more information, see Section 1. Why am I being given CERVIDIL? in the full CMI.

2. What should I know before I am given CERVIDIL?

CERVIDIL should not be used if you have ever had an allergic reaction to dinoprostone, urethane, or any of the ingredients listed at the end of the CMI.
There are several circumstances in which CERVIDIL should not be used or when it should only be used with additional caution.
Talk to your doctor if you have any other medical conditions or take any other medicines.

For more information, see Section 2. What should I know before I am given CERVIDIL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CERVIDIL and affect how it works. This includes aspirin and other NSAIDs.
Refer to Section 3. What if I am taking other medicines? in the full CMI for more information.

You must not be given CERVIDIL if you are being given, or will be given within the next 30 minutes, other medicines to make your womb contract or bring on (induce) labour, e.g. oxytocin.

4. How will I be given CERVIDIL

- **CERVIDIL must only be used in a hospital setting by healthcare professionals trained in the care of women and babies during pregnancy and childbirth.** Facilities for continuous monitoring of you and your baby must be available.
- While you are lying down, your doctor or midwife will place one pessary next to the cervix in your vagina.
- The active ingredient dinoprostone will be released from CERVIDIL until it is removed by your doctor or midwife, up to a maximum of 24 hours after it was first given to you.

More information can be found in Section 4. How will I be given CERVIDIL? in the full CMI.

5. What should I know while using CERVIDIL?

Things you should do	• Tell your doctor or midwife if you experience any nausea or vomiting or if you feel unwell in other ways. They may decide to remove the pessary if you have adverse effects.
Things you should not do	• Do not remove the pessary yourself. CERVIDIL should only be inserted and removed by trained healthcare professionals.

For more information, see Section 5. What should I know while using CERVIDIL? in the full CMI.

6. Are there any side effects?

CERVIDIL may contribute to increased or abnormal contractions of the womb, with possible effects on the progress of your labour, or on you or your baby. The effects on you or your baby may depend on the strength of your contractions. For more information, see Section 6. Are there any side effects? in the full CMI.

Use of CERVIDIL may also contribute to other risks of having labour induced, including heavy vaginal bleeding, inflammation of the membranes lining the inside of the womb, or the risk of a serious condition affecting blood clotting, known as Disseminated Intravascular Coagulation (DIC).

Other side effects can include headache, decrease in blood pressure, itching, swelling or feeling of burning in the genitals, fever, abdominal pain, nausea, vomiting, or diarrhoea. Allergic reactions, including anaphylaxis, have also been reported.

CERVIDIL®

Active ingredient: *dinoprostone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CERVIDIL. **You should also speak to your doctor or midwife if you would like further information or if you have any concerns or questions about being given CERVIDIL.**

Where to find information in this leaflet:

1. Why am I being given CERVIDIL?

CERVIDIL can be used to prepare the birth canal in women who require, and have favourable features for, induction of labour after 37 weeks of pregnancy have been completed. It helps the part of the birth canal known as the cervix to soften and open to allow the baby through.

There can be several reasons why you might need treatment with CERVIDIL. Ask your doctor if you would like to know more.

CERVIDIL contains the active ingredient dinoprostone, also known as Prostaglandin E2 or PGE2. PGE2 also occurs naturally in the body and has an important role during childbirth.

CERVIDIL comes in the form of a pessary (vaginal insert) which is placed in the vagina before the start of labour.

The pessary is held within a pouch attached to a withdrawal tape. Pouch and tape are made of knitted polyester yarn.

When placed in the vagina, the pessary takes up some of the moisture there. This allows the active ingredient, dinoprostone, to be released at a constant rate until the pessary is removed by your doctor or midwife by pulling the withdrawal tape.

CERVIDIL must only be used in a hospital setting by healthcare professionals trained in the care of women and babies during pregnancy and childbirth. Facilities for continuous monitoring of you and your baby must be available.

Ask your doctor or midwife if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed CERVIDIL for another reason.

2. What should I know before I am given CERVIDIL?

Warnings

CERVIDIL should not be used if:

- you are allergic to dinoprostone, or any of the ingredients (e.g. urethane) listed at the end of this leaflet

  Always check the ingredients to make sure you can use this medicine.
- you have had previous womb surgery, including caesarean section, or rupture of the cervix or the womb
- you have had unexplained vaginal bleeding during this pregnancy
- you are carrying more than one baby
- there is any reason why you should not have a vaginal delivery, e.g., active genital herpes or if the placenta is blocking the birth canal
- your baby's head is too big, or the size of your pelvis is too small for a vaginal delivery
- your baby is not in the normal position for birth, including
  - if your baby is in a breech position (not head down into the pelvis)
- you have untreated pelvic inflammatory disease (an infection in the womb, ovaries, tubes and/or cervix)
- it is suspected, or tests show, your baby is unwell or not growing.

Your doctor will not give you CERVIDIL or will remove it after it has been given to you:

- if your contractions are too strong or prolonged
- if your baby becomes distressed
- once labour starts
- if you experience nausea or vomiting, if your blood pressure drops, or if you have an elevated heart rate
- if, following insertion your cervix still hasn't softened and opened enough in 24 hours
- if you need to be given a medicine such as oxytocin to help your labour progress.

There is limited experience of using CERVIDIL if your waters have already broken. Your doctor will remove CERVIDIL after it has been given to you if your waters break or are going to be broken by the doctor.

Check with your doctor if you:

- had difficulties or unusually strong or prolonged contractions delivering a previous baby
- have had more than three full term deliveries
- have or have had any other medical conditions, such as:
  - problems with your heart or blood pressure
  - glaucoma (raised pressure in the eye)
  - epilepsy
  - asthma
  - liver, lung or kidney disease.
- are 35 years or older or younger than 18 years of age
- have had complications during this pregnancy, e.g. gestational diabetes, low blood pressure, thyroid problems, or if your pregnancy has passed 40 weeks

- take any medicines for any other condition (see Section 3. What if I am taking other medicines?).

You will be examined carefully before being given CERVIDIL to determine if CERVIDIL is the right treatment for you. This will include a vaginal examination to check the condition of your cervix and whether the membranes around the baby are intact.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

CERVIDIL is used to help start the birth process provided that 37 weeks of pregnancy have been completed. CERVIDIL should not be used at other phases of pregnancy.

The use of CERVIDIL during breastfeeding has not been investigated. A small amount of the active ingredient in CERVIDIL may pass into breastmilk for a short time but this should not hinder breastfeeding. No effects on the breastfed newborn have been observed.

3. What if I am taking other medicines?

Tell your doctor or midwife if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

You must not be given CERVIDIL if you are being given, or will be given within the next 30 minutes, other medicines to make your womb contract or bring on (induce) labour, e.g. oxytocin.

You should also stop taking aspirin or any other non-steroidal anti-inflammatory drugs (known as NSAIDs) before CERVIDIL is used. Some examples of NSAIDs are naproxen, diclofenac and ibuprofen.

Check with your doctor or midwife if you are not sure about what medicines, vitamins or supplements you are taking and if these could affect CERVIDIL.

4. How will I be given CERVIDIL

How much you will be given

- CERVIDIL is given as one pessary placed into the vagina once only.
- Dinoprostone is slowly released from the CERVIDIL pessary while it remains in place.
- Use of a second pessary is not recommended as the effects of a second dose have not been studied.

When you will be given CERVIDIL

- You will be given CERVIDIL when you have completed at least 37 weeks of pregnancy and before your labour has started.
- CERVIDIL is used to help start the birth process. There can be several reasons why you might need help to start this process. Ask your doctor or midwife if you would like to know more.

How you are given CERVIDIL

CERVIDIL must only be used in a hospital setting by healthcare professionals trained in the care of women and babies during pregnancy and childbirth. Facilities for continuous monitoring of you and your baby must be available.

Your doctor or midwife will place one pessary next to the cervix in your vagina. You should not do this yourself. Your doctor or midwife will coat the pessary with a small amount of lubricating jelly before putting it in place. Enough of the withdrawal tape will be left outside the vagina, so that the pessary can be easily pulled out when it is time to remove it.

You should be lying down during this procedure and you will have to stay that way for about 30 minutes after the pessary is put in.

When placed in position, the pessary takes up some of the moisture there. This allows the dinoprostone to be slowly released.

When CERVIDIL will be removed

Your doctor or midwife will decide how long CERVIDIL needs to be kept in place, depending on your progress. CERVIDIL can be left in place for a maximum of 24 hours.

For example, they may remove the CERVIDIL pessary if:

- your uterus is contracting too strongly
- your labour has started
- your waters have broken
- your doctor wants to use a different medicine to help your womb contract, e.g. oxytocin
- you or your baby is experiencing adverse effects.

Your doctor or midwife will remove the pessary by gently pulling the withdrawal tape.

On removal from the vagina the pessary will have swollen to 2-3 times of its original size and will be pliable.

5. What should I know while using CERVIDIL?

Things you should do

CERVIDIL can be left in place for a maximum of 24 hours depending on your progress. Whilst the pessary remains in place, you will be examined regularly amongst other things for:

- opening of your cervix
- uterine contractions
- the continuing health of you and your baby.

Tell your doctor or midwife if you experience any nausea or vomiting or if you feel unwell in other ways. They may decide to remove the pessary if you have adverse effects.

Things you should not do

Do not remove the pessary yourself. CERVIDIL should only be inserted and removed by trained healthcare professionals.

Looking after your medicine

CERVIDIL is kept in a freezer and removed from the freezer immediately before use. It is stored in the hospital.

Getting rid of any unwanted medicine

The used pessary will be disposed of by the hospital as clinical waste.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or midwife if you have any further questions about side effects.

Tell your doctor or midwife if you notice any of the following and they worry you:

- headache
- itching
- feeling of burning in the genitals
- fever
- abdominal pain
- nausea
- vomiting
- diarrhoea.

These side effects are not usually serious but can become serious. **Talk to your doctor or midwife if you have any concerns.**

Some side effects will be monitored by your healthcare team, for example:

- discoloured amniotic fluid
- decrease in blood pressure
- slow progress of the birthing process
- slow shrinking of the womb after delivery
- swelling of the genitals.

Some side effects can be serious, for example:

- increased or abnormal contractions of the womb which may or may not affect the baby
- placenta detaches from the wall of the womb before the baby is delivered
- heavy bleeding from the vagina following delivery
- hypersensitivity reaction and severe allergic reactions (anaphylactic reaction), which can include: difficult breathing, shortness of breath, weak or rapid pulse, dizziness, redness of skin and rash
- Disseminated Intravascular Coagulation (DIC), a rare condition which affects blood clotting and can lead to serious bleeding, possibly from multiple sites
- anaphylactoid syndrome of pregnancy, a rare condition caused when the amniotic fluid that surrounds the baby in the womb passes into the mother's bloodstream during delivery and blocks a blood vessel. This can lead to shortness of breath, low blood pressure, anxiety, chills, seizures, coma, bleeding and fluid in the lungs.

Possible effects on your baby:

- signs of distress, e.g. heart rate faster or slower than normal
- depressed Apgar score (measures how well the baby is doing immediately after birth)
- difficulty breathing after birth
- jaundice (yellowing of skin and eyes).

These are very serious side effects, which can be life-threatening. They need urgent medical attention.

Your doctor and midwife will monitor you and remove the CERVIDIL pessary if your contractions become too strong. If contractions become too strong, there are risks to both the mother and baby, e.g. tearing of the womb and fetal distress which in very severe cases can result in loss of the baby.

Tell your doctor or midwife if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop using any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CERVIDIL contains

Active ingredient (main ingredient)	Dinoprostone
Other ingredients (inactive ingredients)	The active ingredient is contained in a plastic (polyurethane) sustained release pessary made of: • hexanetriol/macrogol 8000 / isocyanate cross-linked hydrogel copolymer.
Potential allergens	Urethane

The pessary is held within a pouch attached to a withdrawal tape. Pouch and tape are made of knitted polyester yarn.

Do not take this medicine if you are allergic to any of these ingredients.

What CERVIDIL looks like

The CERVIDIL pessary is a small piece of plastic in the shape of a rectangle with rounded corners, contained in a knitted retrieval system (in the pouch with the withdrawal tape). The plastic piece is a hydrogel polymer which swells in the presence of moisture to release dinoprostone. The retrieval system has a long tape which allows the doctor or midwife to remove it when necessary.

CERVIDIL contains 10 mg dinoprostone as a pessary in an aluminium/polyethylene foil sachet. Each sachet contains 1 pessary (AUST R 81391).

Who distributes CERVIDIL

CERVIDIL is distributed in Australia by:

Ferring Pharmaceuticals Pty Ltd
Suite 2, Level 1, Building 1
20 Bridge Street
Pymble, NSW 2073

This leaflet was prepared in September 2022.

DOCS#37784-v4E