

Prostin® E2 Vaginal Gel

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 Prostin E2 Vaginal Gel?

Prostin E2 Vaginal Gel contains the active ingredient dinoprostone. Prostin E2 Vaginal Gel can be used to bring on (induce) labour in pregnant women whose baby position and womb (cervix) characteristics are suitable. It works by softening and opening the entrance of the womb (cervix) and stimulating contractions, which can start labour.

For more information, see Section [1. Why am I being given Prostin E2 Vaginal Gel?](#) in the full CMI.

2. What should I know before I am given Prostin E2 Vaginal Gel?

You should not be given Prostin E2 Vaginal Gel if you have ever had an allergic reaction to it or any of the ingredients listed at the end of the CMI; you have given birth 5 or more times; have had previous surgery

involving the womb; the head of the baby is too big/your pelvis is too small for a normal delivery; any evidence that the baby is unwell or not growing; the baby's head is not well down in the pelvis or is not in the normal position for birth; you have had unexplained vaginal discharge or bleeding during the current pregnancy; vaginal delivery is not suitable e.g. active genital herpes; you are carrying more than one baby or if you have been given other medicines that are used to make the muscles of your womb contract at the same time e.g. oxytocin.

Talk to your doctor if you have any other medical conditions including heart, liver or kidney problems, asthma, epilepsy or glaucoma (high pressure in the eye); take any other medicines; if your membranes have ruptured (water has broken); you are over 35 years of age; you are over 40 weeks pregnant; or are breastfeeding or intend to breastfeed.

For more information, see Section [2. What should I know before I am given Prostin E2 Vaginal Gel?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Prostin E2 Vaginal Gel and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Prostin E2 Vaginal Gel given?

Prostin E2 Vaginal Gel is given in the vagina while you are lying down. You should stay lying down for at least 30 minutes after you are given Prostin E2 Vaginal Gel. It should only be used under the supervision of healthcare professionals trained in the care of women and babies during pregnancy and childbirth. You and your baby should be closely monitored.

More instructions can be found in Section [4. How is Prostin E2 Vaginal Gel given?](#) in the full CMI.

5. What should I know while being given Prostin E2 Vaginal Gel?

Things you should do	<ul style="list-style-type: none">• You should stay lying down for at least 30 minutes after you are given Prostin E2 Vaginal Gel. During this time, your contractions and the baby's heart
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	<p>rate are monitored.</p> <ul style="list-style-type: none"> • Tell your doctor or midwife as soon as possible if you do not feel well or experience excessive pain after being given Prostin E2 Vaginal Gel.
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For more information, see Section [5. What should I know while being given Prostin E2 Vaginal Gel?](#) in the full CMI.

6. Are there any side effects?

Speak to your doctor or midwife if you have any of these side effects and they worry you: nausea, vomiting; diarrhoea; back pain; itching, burning/warmth, redness, swelling of the vagina; fever; facial flushes; shivering; dizziness; fast dilation of the cervix.

Inform your doctor or midwife straight away if you notice: excessive frequency or strength of contractions or any bleeding; headache; nose bleeds; difficulty breathing; stomach or chest pain; blurred vision; sudden signs of allergy (which may include shortness of breath,

wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash; itching or hives on the skin); dizziness or feeling faint; infection; a severe allergic response to amniotic fluid mixing with your blood, heavy bleeding after the baby has been born, breaking of the placenta or uterus and heart attack are rare but possible; fetal distress and still births have been reported.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Prostin® E2 Vaginal Gel

Active ingredient(s): *dinoprostone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Prostin E2 Vaginal Gel. **You should also speak to your doctor or midwife if you would like further information or if you have any concerns or questions about using Prostin E2 Vaginal Gel.**

Where to find information in this leaflet:

- [1. Why am I being given Prostin E2 Vaginal Gel?](#)
- [2. What should I know before I am given Prostin E2 Vaginal Gel?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Prostin E2 Vaginal Gel given?](#)
- [5. What should I know while being given Prostin E2 Vaginal Gel?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given Prostin E2 Vaginal Gel?

Prostin E2 Vaginal Gel contains the active ingredient **dinoprostone** which acts like a natural substance in your body called **prostaglandin E2**.

Prostin E2 Vaginal Gel can be used to bring on (induce) labour in pregnant women whose baby position and womb (cervix) characteristics are suitable. It works by softening and opening the entrance of the womb (cervix) and stimulating contractions, which can start labour.

Your doctor may have prescribed Prostin E2 Vaginal Gel for another reason. Ask your doctor if you have any questions about why Prostin E2 Vaginal Gel has been prescribed for you.

2. What should I know before I am given Prostin E2 Vaginal Gel?

Warnings

Prostin E2 Vaginal Gel should not be used if:

- you are allergic to dinoprostone, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
- you have given birth 5 or more times
- you have had previous surgery involving the womb
- the head of the baby is too big or your pelvis is too small for a normal delivery
- there has been any evidence that the baby is unwell or not growing

- the baby, and particularly the head, is not in the normal position for birth
- the baby's head is not well down in the pelvis
- if you have had unexplained vaginal discharge or bleeding during the current pregnancy
- vaginal delivery is not suitable e.g. active genital herpes
- you are carrying more than one baby.
- you have been given other medicines that are used to make the muscles of your womb contract at the same time e.g. oxytocin

Check with your doctor if you:

- have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
- Have or have had any other medical conditions
 - heart, liver or kidney problems
 - asthma
 - epilepsy (fits)
 - glaucoma (high pressure in the eye).
- take any medicines for any other condition
- if your membranes have ruptured (also known as water breaking)
- if you are over 35 years of age
- if you are over 40 weeks pregnant

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?](#)

Breastfeeding

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor, midwife or pharmacist 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.

Some medicines and Prostin E2 Vaginal Gel may interfere with each other. These include a group of medicines called oxytocics that are used to make the muscles of your womb contract or bring on labour.

Check with your doctor, midwife or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these could affect Prostin E2 Vaginal Gel.

4. How is Prostin E2 Vaginal Gel given?

How it is given

- Prostin E2 Vaginal Gel should only be used under the supervision of healthcare professionals trained in

the care of women and babies during pregnancy and childbirth.

- Prostin E2 Vaginal Gel comes in a pre-filled syringe applicator. The syringe applicator is inserted gently into the vagina and the gel is released while you are lying down. You should stay lying down for at least 30 minutes after you are given Prostin E2 Vaginal Gel.

How much is given

- Your doctor will decide what dose you will receive and how often.

5. What should I know while being given Prostin E2 Vaginal Gel?

Things you must do

- You should stay lying down for at least 30 minutes after you are given Prostin E2 Vaginal Gel. During this time, your contractions and the baby's heart rate are monitored.
- Tell your doctor or midwife as soon as possible if you do not feel well while you are given Prostin E2 Vaginal Gel or experience excessive pain.

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.

Side effects

Side effects	What to do
<ul style="list-style-type: none">• nausea, vomiting and diarrhoea• back pain• itching, burning or warmth, redness and swelling of the vagina• fever• facial flushes• shivering or dizziness• fast dilation of the cervix	Speak to your doctor or midwife if you have any of these side effects and they worry you.

Side effects	What to do
<ul style="list-style-type: none">• excessive frequency or strength of contractions or any bleeding• headache or nose bleeds• difficulty in breathing• stomach or chest pain• blurring of vision	Inform your doctor or midwife straight away if you notice any of these serious side effects.

Side effects	What to do
<ul style="list-style-type: none"> • sudden signs of allergy which may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash; itching or hives on the skin • dizziness or feeling faint • infection • a severe allergic response to amniotic fluid mixing with your blood, heavy bleeding after the baby has been born, breaking of the placenta or uterus and heart attack are rare but possible • fetal distress and still births have been reported 	

Tell your doctor, midwife or pharmacist 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/safety/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, midwife or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Prostin E2 Vaginal Gel contains

Active ingredient (main ingredient)	dinoprostone
Other ingredients (inactive ingredients)	colloidal anhydrous silica triacetin

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

What Prostin E2 Vaginal Gel looks like

Prostin E2 Vaginal Gel is a thick, colourless and clear gel in a syringe. It comes in two strengths:

- 1 mg gel: AUST R 9983
- 2 mg gel: AUST R 9984

Where is Prostin E2 Vaginal Gel stored

Prostin E2 Vaginal Gel will be stored in the pharmacy or on the ward.

Who distributes Prostin E2 Vaginal Gel

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in December 2025.

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