

PROSTIN(R) E2 Vaginal Gel

Dinoprostone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PROSTIN E2.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given PROSTIN E2 against the benefits they expect it to provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What PROSTIN E2 is used for

PROSTIN E2 can be used to bring on (induce) labour in women who have a normal pregnancy. It works by softening and dilating the neck of the womb and stimulating contractions.

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

This medicine is available only with a doctor's prescription. It is not addictive.

Before you are given PROSTIN E2

Your doctor will decide if PROSTIN E2 is suitable for you.

When you must not be given it

You should not be given PROSTIN E2:

- * at the same time with other drugs that are used to make the muscles of your womb contract eg. oxytocin.
- * if you have an allergy to dinoprostone, the active ingredient or any of the ingredients listed at the end of this leaflet.
- * if the packaging is torn or shows signs of tampering.
- * after the expiry date (EXP) printed on the pack.
- * if you have given birth 5 or more times.
- * if the baby's head is not well down in the pelvis.
- * if you have had previous surgery involving the womb.
- * if the head of the baby is too big or your pelvis is too small for a normal delivery.
- * if there has been any evidence that the baby is unwell or not growing.
- * if the baby is not in the normal position for birth.
- * if you have had unexplained vaginal discharge or bleeding during the current pregnancy.

- * if vaginal delivery is not suitable eg. herpes genitalis.
- * if you are carrying more than one fetus.

If you are not sure whether you should be given PROSTIN E2, talk to your doctor.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- * any other medicines
- * any other substances, such as foods, preservatives or dyes

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- * heart, liver or kidney problems
- * asthma
- * epilepsy (fits)
- * glaucoma (high pressure in the eye).

If you have not told your doctor or pharmacist about any of the above, tell them before you are given PROSTIN E2.

Taking other medicines

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

Some medicines and PROSTIN E2 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.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while using PROSTIN E2.

How PROSTIN E2 is given

How much is given

Your doctor will decide what dose you will receive.

How it is given

PROSTIN E2 is inserted into the vagina. It must only be given under the supervision of a doctor.

Overdose

Your doctor or pharmacist has information on how to recognise and treat an overdose. Ask your doctor or pharmacist if you have any concerns.

While you are being given PROSTIN E2

Things you must do

You should lie on your side for at least 30 minutes after you are given PROSTIN E2. During this time, your contractions and the baby's heart rate are monitored.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are having PROSTIN E2.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need

medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

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

- * nausea, vomiting and diarrhoea
- * back pain
- * vaginal irritation

Tell your doctor immediately if you notice any of the following:

- * excessive frequency or strength of contractions or any bleeding

Sometimes a very small amount of this drug could be absorbed into the body and the following side effects may be seen:

- * fever
- * high blood pressure
- * difficulty in breathing
- * headache
- * stomach pain
- * chest pain
- * blurring of vision
- * facial flushes
- * 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.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Storing PROSTIN E2

Storage

PROSTIN E2 will be stored in the pharmacy or on the ward.

Product description

What it looks like

PROSTIN E2 is a thick, colourless and clear gel.

Ingredients

The active ingredient in PROSTIN E2 is dinoprostone.

PROSTIN E2 also contains silica - colloidal anhydrous and glycerol triacetate.

Identification

PROSTIN E2 vaginal gel can be identified by the Australian Register Number on the box:

1 mg gel: AUST R 9983

2 mg gel: AUST R 9984

Supplier

PROSTIN E2 vaginal gel is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Australia

Toll Free number: 1800 675 229

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This leaflet was prepared in July 2000 and updated in January 2005.