Patient leaflet: Information for the user
Prostin® E2 3 mg Vaginal Tablets
dinoprostone

[Pfizer Logo]

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, midwife or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to you doctor, midwife or pharmacist. This includes any possible side not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Prostin E2 Vaginal Tablets are and what they are used for

Prostin E2 Vaginal Tablets contain the prostaglandin dinoprostone and are used to "induce" labour. This means that the medicine will help your uterus (womb) to start contracting and you will go into labour. Dinoprostone is similar to the natural 'E2', type of prostaglandins which are made in your body when labour starts. It will only be given to you in a hospital or clinic which has an obstetric and maternity unit.

2. What you need to know before you are given Prostin E2 Vaginal Tablets

Most women can be treated with Prostin E2 Vaginal Tablets. Some women may need extra checks during treatment and for some women a different treatment may be better. Your doctor or midwife will ask you questions before giving you Prostin E2 Vaginal Tablets to make sure they are safe for you. If you do not understand any of the questions, ask your doctor or midwife to explain.

Do not use Prostin E2 Vaginal Tablets:

- If you are allergic to dinoprostone or any other prostaglandin or any of the other of this medicine (listed in section 6). Signs of hypersensitivity include wheezing, breathlessness, swelling of the hands, face, itchy rash or redness of the skin.
- If you have heart, lung, kidney or liver disease.

Your doctor or midwife will not use Prostin E2 to start or strengthen your labour in certain circumstances if:

- you have had a Caesarean section or any major surgery to your womb
- the size of your baby's head means there may be a problem with the delivery
- there has been or there is suspected foetal distress (your baby is short of oxygen)
- you had a difficult labour or traumatic delivery in a previous pregnancy
- you have an infection of your womb, ovaries or tubes (pelvic inflammatory disease) unless you are receiving treatment for these, or if you have ever had such an infection in the past
- you have been told that you have or might have placenta praevia (where the placenta lies across the entrance to the womb, rather than being high up and out of the way during birth). This causes bleeding from the vagina during pregnancy and may require that your baby is delivered by Caesarean section.
- during your pregnancy you have had bleeding from the vagina and the cause of the bleeding is not known
- your baby is not lying with his or her head down or the baby's head is not engaged.
- you are pregnant with more than one baby e.g. twins, triplets
- the risks involved in proceeding with a normal delivery are higher than the benefits to either you or your baby and your doctor feels surgery is more suitable

Warnings and precautions

Talk to your doctor, midwife or pharmacists before you are given Prostin E2 Vaginal Tablets if you have or have had in the past any of the following conditions as they may want to monitor you more closely.

- heart, lung, kidney or liver disease
- glaucoma (raised pressure in the eye)
- epilepsy
- suffered from asthma
- hypertension (high blood pressure) at any time, including during this or any previous pregnancy
- been told you had abnormally strong contractions of your womb during a previous labour
- scarring of your womb from a previous operation
- if you are having more than one baby
- if your water has broken.

Your doctor will need to monitor the activity of your uterus and your baby's heart rate during the use of Prostin.

A higher risk of generalised bleeding disorder following delivery (post-partum disseminated intravascular coagulation (DIC) has been described in women who:

- are 35 years or older
- have history of complications during labour
- have a gestation period of over 40 weeks.

Studies have shown proliferation (thickening) of bone in new-born infants who have been treated with prostaglandins for a long time. There is no evidence that this occurs following short-term treatment with Prostin E2 Vaginal Tablets.

Your doctor or midwife will ask you questions before giving you Prostin E2 Vaginal Tablets to make sure they are safe for you.

If you do not understand any of the questions, ask your doctor or midwife to explain.

Other medicines and Prostin E2 Vaginal Tablets

Tell your doctor, pharmacist or midwife if you are taking, have recently taken or might take any other medicines.

Prostin E2 Vaginal Tablets can make you more sensitive to another medicine called oxytocin which is used to strengthen contractions. Medical staff will normally try not to use this medicine at the same time as Prostin E2 Vaginal Tablets. If you need this medicine, your doctor or midwife will make sure they are not given to you close together and will watch over the contractions very carefully.

Pregnancy, breast-feeding and fertility
Prostin E2 Vaginal Tablets will only be given to you in the late stages of pregnancy to induce labour.

Although prostaglandins are present in breast milk they will not harm your baby and you may breast-feed as normal after delivery.

Driving and using machinery
No effect on your ability to drive or use machinery is expected after being given Prostin E2 Vaginal Tablets.

3. How Prostin E2 Vaginal Tablets are given to you

Prostin E2 Vaginal Tablets will be given to you by a trained professional in a hospital or clinic where facilities for monitoring you and your baby are available.

The first dose is one tablet placed high up in the vagina. If you have not had any contractions after 6 hours, a second tablet may be used. You should not be given any more tablets for 24 hours.

Your doctor or midwife will do internal checks to make sure that your cervix is opening enough. They will also check your contractions (to make sure that they are not too strong) and your baby (to make sure he or she does not get distressed).

Your doctor or midwife should be keeping a very close eye on you during your treatment. They should be able to act quickly if you have side-effects or if your womb reacts too strongly to the dose you are given.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you have asthma, Prostin E2 Vaginal Tablets could cause you to have an asthmatic attack. **You must tell your doctor or midwife if you suffer from asthma or if you have difficulty breathing.**

Rare: may affect up to 1 in 1,000 people
Rare but serious side effects which can sometimes happen include the following:

- tearing or bursting of the wall of your womb (uterine rupture)

- heart attack
- allergic reactions (symptoms may include wheezing, breathlessness, swelling of the hands, face, itchy rash or redness of the skin).

If you get any of these symptoms please tell your doctor or midwife straight away.

Common: may affect up to 1 in 10 people
- vomiting (being sick)
- nausea (feeling sick)
- diarrhoea.

These have seldom been bad enough for the woman to stop the treatment.

Not known: frequency cannot be estimated from the available data
Women having prostaglandin E2 vaginally have experienced the following problems. These problems have also been seen in women not taking prostaglandins and include:

- sudden blocking of a blood vessel with amniotic fluid (the fluid which surrounds the baby) or by a blood clot in the lungs. This could cause chest pain and shortness of breath
- placenta becoming detached
- abnormally strong, frequent or long contractions of the womb, slowing or quickening of the baby's heart rate and distress in the baby
- feeling of warmth of the vaginal area
- high blood pressure in the mother
- very quick opening of the cervix
- running a high temperature
- backache
- rash
- neonatal distress
- severe bleeding disorder
- foetal death, stillbirth and death of the newborn baby (neonatal death); especially following serious events such as tearing of the womb.

Reporting of side effects
If you get any side effects or you are worried about anything unusual happening during your labour, talk to your doctor, pharmacist or midwife. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prostin E2 Vaginal Tablets

The medicine will be kept out of the sight and reach of children.

Prostin E2 Vaginal Tablets will not be given to you after the expiry date which is stated on the blister packs after 'Use before'. The expiry date refers to the last day of that month.

Your hospital pharmacist will store this medicine in a refrigerator at 2 to 8 °C.
This medicine will be stored in the original package in order to protect from moisture.

6. Content of the pack and other information

What Prostin E2 Vaginal Tablets contains

The active substance is called dinoprostone. Each tablet contains 3 mg (milligrams) of dinoprostone. The other ingredients are lactose anhydrous, microcrystalline cellulose, maize starch, magnesium stearate and colloidal silica anhydrous.

What Prostin E2 Vaginal Tablets look like and contents of the pack

Prostin E2 Vaginal Tablets are white, biconvex, special shaped tablets, embossed with Upjohn 715 one side and plain on the other.
Prostin E2 Vaginal Tablets are packed in blister packs of 4 and 8 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Pfizer Healthcare Ireland
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24.

Manufacturer:
Sanico NV
Veedijk 59
Turnhout, 2300
Belgium

Company contact address:

For further information on your medicine contact Medical Information at the following address:
Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland
Telephone: 1-800 633 363.

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