

## **Package leaflet: Information for the patient**

### **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.

If you get any side effects, talk to your doctor, midwife or pharmacist. This includes any possible side effects 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
2. What you need to know before you are given Prostin E2 Vaginal Tablets
3. How Prostin E2 Vaginal Tablets are given to you
4. Possible side effects
5. How to store Prostin E2 Vaginal Tablets
6. Contents of the pack and other information

#### **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 a specialised obstetric 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 ingredients of this medicine (listed in section 6). Signs of an allergic reaction include wheezing, breathlessness, swelling of the hands, face, itchy rash or redness of the skin.

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

- you have had a Caesarean section or any major surgery to your womb.
- you have been told that your baby is too big for your pelvis, is lying awkwardly or may be physically stressed.
- 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.

- you have had unexplained bleeding from the vagina or spotting at any time during your pregnancy.
- you have current heart, lung, kidney or liver disease.

### **Warnings and precautions**

Talk to your doctor or midwife before they use this medicine 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
- are you 35 years or older?
- is your pregnancy over 40 weeks?
- do you have any complications related to this pregnancy?
- an increased risk of developing a generalised bleeding disorder, a condition known as post-partum disseminated coagulation
- if you are having more than one baby
- if your water has broken.

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 or pharmacist 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 and breast-feeding**

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.

## **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. Before you are given this medicine, you will be examined by your doctor or midwife. They need to know the position of your baby's head and how dilated (wide) your cervix (neck of the womb) is.

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.

The doctor or nurse will keep a very close eye on you during your treatment to make sure that the contractions do not become too strong, as this could cause your uterus to tear. 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. You might just need a lower dose, or you might need some other obstetric procedure.

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 they do not get distressed).

#### **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 by causing a narrowing of your airways (bronchospasm). **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/anaphylactic reactions, including anaphylactic shock (serious allergic reactions which can include skin rash, itching, wheezing, shortness of breath, swollen face, lips, hands, fingers, neck and throat, sudden drop in blood pressure, abdominal pain and collapse).

**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.

#### **Not known: frequency cannot be estimated from the available data**

As prostaglandins make the body go into labour in the same way as it would happen naturally, anything that can happen in a natural labour can also happen if you have been given Prostin E2 Vaginal Tablets. This includes:

- Sudden blockage of a blood vessel with amniotic fluid (the fluid which surrounds the baby) or by a blood clots in the lungs. This could cause chest pain and shortness of breath.
- Placenta becoming detached
- Foetal death, stillbirth and death of the new born baby (neonatal death); especially following serious events such as tearing of the womb.
- Abnormally strong, frequent or long contractions of the womb
- Slowing or quickening of the baby's heart rate and distress in the baby
- Itching, soreness, rash or 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

- Baby born with an Apgar score lower than seven. (The Apgar score, which is measured on a scale of one to ten, is used to describe the baby's condition at birth. A low Apgar score means that the baby's heart or lungs are not working properly.)

Talk to your doctor or midwife about this if you want to know more, as they will be able to give you the information that you need.

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.

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

- are aged 35 and above.
- whose pregnancies are more than 40 weeks.
- who have pregnancy-related complications.

### **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, midwife or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Prostin E2 Vaginal Tablets**

Keep this medicine 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 carton after EXP. The expiry date refers to the last day of that month.

The hospital pharmacist will store this medicine in a refrigerator at 2-8 °C. Where the tablets are supplied in a bottle, the tablets should be used within one month of opening the bottle.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Prostin E2 Vaginal Tablets contain**

The active substance is dinoprostone. Each tablet contains 3 mg of dinoprostone.

The other ingredients are lactose, microcrystalline cellulose, maize starch, magnesium stearate and colloidal silicon dioxide.

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

Each pack contains either:

- one amber glass bottle with screw cap and tac seal containing a desiccant capsule and 4 tablets or
- blister packs of 4 or 8 tablets.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Pfizer Limited  
Ramsgate Road  
Sandwich  
Kent  
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### **Manufacturer**

Sanico NV  
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For any information on this medicine, please contact Pfizer Medical Information on: 01304 616161.

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