Dosage and administration

Directions for the Preparation of a Dilute Solution: For use by i.v. drip (a drip set delivering 60 drops per ml must be used) or constant rate infusion pump. Withdraw 0.5 ml from the ampoule using an aseptic technique and add to 1,000 ml of sterile normal saline or 5% dextrose. Shake to ensure uniformity.

After dilution, attach label provided. Use dilute solution within 24 hours of preparation and store in a refrigerator at 2-8°C.

The following is a guide to dosage:
A solution of Prostin E2 in normal saline or 5% dextrose containing 5.0 micrograms per ml should be prepared in accordance with instructions given above. The initial rate of infusion (p.i., i.v. drip delivering 60 drops per ml) will be 2.5 micrograms per minute, and this rate should be maintained for at least the first 30 minutes. If a satisfactory uterine contractility response is produced, the rate should be maintained, if not, the rate should be increased to 5 micrograms per minute. If satisfactory uterine activity is not produced after at least 4 hours at this rate of infusion, the rate may be increased up to 10 micrograms per minute, side-effects permitting, and maintained until abortion occurs or the treatment is considered a failure. If significant side-effects occur, the rate of infusion should be decreased by 50% or discontinued.

If a constant rate infusion pump is used, a different concentration of solution (e.g. 15 micrograms per ml) may be required, dependent on the type of pump, but the dose rates (micrograms per minute) should remain as above. The appearance of uterine hypertonus requires cessation of therapy until the state returns to normal. The situation should be re-assessed and, if necessary, the infusion can be recommenced, but at lower dose rates, 50% of the last dose level used.

In all cases the dosage should be adapted to the patient’s response. Continuous administration of the drug for more than two days is not recommended.

Contra-indications, warnings etc.

Children and elderly patients: Not applicable

Prostaglandin treatment is not recommended in the following circumstances:
1. For patients in whom oxytocic drugs are generally contra-indicated or where progressed contractions of the uterus are considered inappropriate such as:
   - Cases with a history of Caesarean section or major uterine surgery;
   - Where there is evidence of a potential for obstructed labour.
2. In patients with a past history of, or existing, pelvic inflammatory disease, unless adequate prior treatment has been instituted.
3. Patients with active cardiac, pulmonary, renal or hepatic disease.

Interactions with other medications and other forms of interaction: Since it has been found that prostaglandins potentiate the effect of oxytocin, it is not recommended that these drugs are used together. If used in sequence, the patient’s uterine activity should be carefully monitored.

Effects on ability to drive and to use machines: Not applicable.

Other undesirable effects:
Cardiac disorders: Cardiac arrest
Vascular disorders: Hypertension
Gastro-intestinal disorders: Diarrhoea, nausea, vomiting
General disorders and administration site conditions: Fever, local tissue irritation / erythema (injection site), temporary pyrexia, local infections
Immune system disorders: Hypersensitivity reactions such as anaphylactoid reactions and anaphylactic reactions including anaphylactic shock.

Your doctor or nurse will ask you questions before giving you Prostin E2 to make sure it is safe for you.

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

Taking other medicines:
Prostin E2 Sterile Solution 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 Sterile Solution. If used with this medicine in sequence, your doctor or nurse will watch over the womb contractions very carefully.

Your doctor may give you antibiotics before you start this prostaglandin treatment.

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breastfeeding
Prostin E2 will only be given to you in the late stages of pregnancy to induce labour.
Prostin E2 Sterile Solution is only used during pregnancy for therapeutic termination of pregnancy, missed abortion and hydatidiform mole.

Although prostaglandins are present in breast milk, you are not expected to be breast-feeding as this medicine is used to terminate the pregnancy.

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

3. How Prostin E2 Sterile Solution is given to you
This product can only be used in hospitals and clinics with specialised units for pregnancy and childbirth (obstetric units). Medical staff will be available at all times.

Prostin E2 Sterile Solution is diluted before use with a 5% dextrose (dextrose) solution and given by an intravenous drip.

Medical staff will adjust the dose to suit you. It depends on why you need the treatment and how you react to it. The mixture is made up to contain 5 micrograms/ml of Prostin E2 Sterile Solution and the drip is set to deliver 2.5 micrograms per minute. This is given for 30 minutes,
Happen include the following:

- Allergic/anaphylactic reactions, including anaphylaxis
- Tearing or bursting of the wall of your womb (uterine rupture)
- Narrowing of your airways (bronchospasm).

Like all medicines Prostin E2 Sterile Solution can cause contractions to make sure that they are not too strong. That your cervix is opening enough. They will also check your blood pressure, abdominal pain and collapse.

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

### Common side effects

- Vomiting (being sick)
- Nausea (feeling sick)
- Diarrhoea

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

### Other side effects

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

These include:

- Vaso-vagal symptoms (flushing, shivering, headache, dizziness, fainting)
- Detached placenta
- Sudden blockage 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.
- Abnormal strong, frequent or long contractions of the womb
- High blood pressure in the mother
- Very quick opening of the cervix
- Running a high temperature

In some women the number of white blood cells rises during delivery (post-partum disseminated intravascular coagulation (DIC)).

If you have asthma, Prostin E2 Sterile Solution could cause you to have an asthma attack by causing a narrowing of your airways (bronchospasm). You must tell your doctor or nurse if you suffer from asthma or if you start having difficulty in breathing.

### Rare side effects

Rare but serious side effects which can sometimes happen include the following:

- Severe allergic reactions, including anaphylactic shock
- Heart attack
- Rash, itching, wheezing, shortness of breath, swollen face, lips, hands, fingers, neck and throat, sudden drop in blood pressure, abnormal pain and collapse.

You might have reddening and irritation in the area around the needle for two to five hours after the needle has been removed.

If you think you may be having any of the above side effects, or you are worried about anything unusual happening during your labour, please tell your doctor or nurse.

### How to store Prostin E2 Sterile Solution

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

Prostin E2 will not be given to you after the expiry date which is stamped on the packs. The expiry date refers to the last day of that month.

Your hospital pharmacist will store this medicine in a refrigerator at 4°C before use.

### Further information

What Prostin E2 Sterile Solution contain:

- The active substance is called dinoprostone. It also contains ethanol (alcohol).

What Prostin E2 Sterile Solution looks like and contents of the pack

Prostin E2 Sterile Solution is available in a pack that contains a small, closed glass container (ampoule) containing 0.5 ml of Prostin E2 Sterile Solution.

### Marketing Authorisation Holder

Pfizer Limited, Ramsigate Road, Sandwich, CT13 9NJ, UK.

### Product authorisation number

PL 000571027

### Date of preparation or last review

12/2014

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