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Package leaflet: information for the user

PROSTENOON-GEEL, 2 mg/3.5 g vaginal gel
Dinoprostone

Read all of this leaflet carefully before you start using 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 or midwife.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or midwife. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What PROSTENOON-GEEL, 2 mg/3.5 g is and what it is used for

The name of the medicine is PROSTENOON-GEEL, 2 mg/3.5 g vaginal gel (further in this leaflet called PROSTENOON-GEEL, 2 mg/3.5 g).

PROSTENOON-GEEL, 2 mg/3.5 g contains dinoprostone (*Dinoprostonum*), which belongs to a group of medicines called prostaglandin analogues. Prostaglandins help to stimulate labour. Dinoprostone induces softening, dilation and opening of the cervix. This process is called „cervical ripening“. Maturity of the cervix is one of the important prerequisites for the labour.

PROSTENOON-GEEL, 2 mg/3.5g is used only in hospital setting for the following reasons:
- Preparation of the immature cervix for induction of labour at term gestation and for medical reasons.

2. What you need to know before you are given PROSTENOON-GEEL, 2 mg/3.5 g

You must not be given PROSTENOON-GEEL, 2 mg/3.5 g:
- if you are allergic to dinoprostone or any of the other ingredients of this medicine

(listed in section 6);
- if you have had a Caesarean section or major uterine surgery;
- if there is a mismatch in size between the fetal head and the maternal pelvis;
- if your baby is not in the correct position in the womb;
- if your unborn baby is in distress or there is a risk for your baby becoming distressed (your baby might suffer from oxygen deprivation during childbirth);
- if you have had complicated labour and/or traumatic delivery;
- if you have had more than five full term pregnancies;
- if your waters have broken (premature rupture of membranes);
- if you have pelvic inflammatory disease (infection of the internal female reproductive organs) and where no adequate prior treatment has been instituted;
- if you have been told that you have or might have placenta praevia;
- if you have had any unexplained vaginal bleeding during the current pregnancy;
- if you have severe heart, lung, kidney or liver disease;
- if you have suffered from too strong contractions in your womb during the previous labour.

If any of the above applies to you, please talk to your doctor or midwife before you are given this medicine.

Warnings and precautions
Please consult with your doctor or midwife before using PROSTENOON-GEEL, 2 mg/3.5 g.
The following reasons demonstrate the cases in which PROSTENOON-GEEL, 2 mg/3.5 g might not be suitable for you:
- if you have glaucoma (an eye disease);
- if you have epilepsy;
- if you have raised intraocular pressure;
- if you have asthma or a history of asthma;
- if you have liver disease;
- if you have kidney disease;
- if you have compromised cardiovascular function.

If any of the above applies to you, please talk to you doctor.

If you are aged 35 or over, if you have had complications during pregnancy, or your pregnancy has lasted more than 40 weeks, then you have an increased risk of developing post-partum disseminated intravascular coagulation (DIC). These factors may further increase other risks associated with labour induction (see section 4). Therefore, use of dinoprostone should be done with extreme caution.

Other medicines and PROSTENOON-GEEL, 2 mg/3.5g
Prostaglandins may potentiate the effect of oxytocin that is used for labour induction and stimulation. If after using PROSTENOON-GEEL, 2 mg/3.5g should occur the need to use oxytocin in sequence, the patient should be carefully monitored.

Tell your doctor or midwife if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

PROSTENOON-GEEL 2 mg/3.5 g with food and drink
Not applicable.

Pregnancy, breast-feeding and fertility
During pregnancy, the use of this medicine may induce miscarriage or premature birth.

Driving and using machines
Not applicable.

3. How you are given PROSTENOON-GEEL, 2 mg/3.5 g

PROSTENOON-GEEL, 2 mg/3.5 g must only be administered to you by qualified medical staff in a hospital or clinic setting with appropriate obstetrical and intensive care facilities available.

The doctor or midwife will place the entire content of the pre-filled syringe of PROSTENOON-GEEL, 2 mg/3.5 g into the posterior vaginal fornix using a sterile catheter included in the package. You should be lying down during this procedure and you should stay in this position for about 15 minutes to minimize the leakage of the gel from the posterior vaginal fornix. Your doctor or midwife will tell you when you can change your position.

If there is insufficient response to the initial dose, the administration of PROSTENOON-GEEL, 2 mg/3.5 g may be repeated in 6 hours after the first dose administration. The need for additional dose and dosing interval will be determined by your doctor.

If you are given more PROSTENOON-GEEL, 2 mg/3.5 g than you should
Overdose is unlikely, because PROSTENOON-GEEL 2 mg/3.5 g is provided in pre-filled single-dose syringe and this medicine is administered only by the medical personnel.
Overdose of PROSTENOON-GEEL, 2 mg/3.5 g can cause uterine hyperactivity. If overdose might happen, your doctor will have the information on how to recognize and treat the possible symptoms. You may be given a medicine to relax the uterus. If relaxing treatment still proves inefficient and changes in the fetal heart rate are detected, the prompt delivery is indicated. Strong and long-lasting uterine contractions have been associated with the possibility of uterine rupture.

If you have any further questions, ask your doctor or midwife.

4. Possible side effects

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

Common side effects (may affect more than 1 woman from 100 , but less than 1 woman from 10): nausea, vomiting, diarrhea, high body temperature (fever), back pain, feeling of warmth in vagina, uterine hypercontractility or hypertonus, irregular uterine contractions with or without changes in the fetal heart rate, fetal distress.

Rare side effects (may affect more than 1 woman from 10 000, but less than 1 woman from 1 000): tear in the wall of uterus (uterine rupture), cardiac arrest, elevated risk of post-partum disseminated intravascular coagulation in patients, whose labour was pharmacologically induced with dinoprostone (see section 2).

Not known (cannot be estimated from the available data):
- pulmonary/amniotic fluid embolism (sudden occlusion of a pulmonary blood vessel by amniotic fluid);
- hypersensitivity reactions such as anaphylactic and anaphylactoid reactions, including anaphylactic shock (a severe allergic reaction manifested by skin rash, itching, wheezing, shortness of breath, swelling of the face, lips, hands, fingers, neck and throat, a sudden drop in blood pressure, abdominal pain and loss of consciousness);
- placental abruption (placenta separates from the wall of the uterus prior to childbirth);
- stillbirth, death of the newborn;
- low Apgar score of the newborn;
- high blood pressure (maternal);
- bronchospasm/asthma;
- rapid dilation of the cervix;
- rash.

If you get any side effects, talk to your doctor or midwife. This includes any possible side effects not listed in this leaflet.

Reporting of side effects
If you get any side effects, talk to your doctor or midwife. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store PROSTENOON-GEEL, 2 mg/3.5 g

Keep out of the reach and sight of children.

This medicine should be stored by a health care provider. You will not be given PROSTENOON-GEEL, 2 mg/3.5 g to store at home. Hospital pharmacist will store this medicine in a refrigerator (2ºC...8ºC).

PROSTENOON-GEEL, 2 mg/3.5 g will not be given to you after the expiry date which is stated on the outer carton and pouch. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What PROSTENOON-GEEL, 2 mg/3.5 g contains

- The active substance is dinoprostone. The single-dose syringe contains 2 mg of dinoprostone in 3,5 g (3.0 ml) of a gel.
- The excipients are anhydrous colloidal silica, propylene glycol, glycerol and ethanol.

What PROSTENOON-GEEL, 2 mg/3.5 g looks like and contents of the pack

PROSTENOON-GEEL, 2 mg/3.5 g is transparent and colourless sterile gel that is marketed in a prefilled single-use syringe provided with protective end cap. Each pack of this medicine contains one sterile syringe and one sterile catheter in two separate pouches.

Marketing Authorisation Holder and Manufacturer

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