

PACKAGE LEAFLET

Package leaflet: Information for the user

PROPESS 10 mg vaginal delivery system

dinoprostone

Read all of this leaflet carefully before you are given 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4
- PROPESS should only be used under the supervision of an appropriate specialist

What is in this leaflet:

1. What PROPESS is and what it is used for
2. What you need to know before you are given PROPESS
3. How you are given PROPESS
4. Possible side effects
5. How to store PROPESS
6. Contents of the pack and other information

1. What PROPESS is and what it is used for

PROPESS contains the active substance dinoprostone 10 mg and is used to help start the birth process provided that 37 weeks of pregnancy have been completed. The dinoprostone opens the part of the birth canal known as the cervix, to allow the baby through. There can be several reasons why you might need help starting this process. Ask your doctor if you would like to know more.

2. What you need to know before you are given PROPESS

Do not use PROPESS

You must not be given PROPESS:

- if the size of your baby's head may cause any problem during delivery
- if your baby is not in the correct position in the womb, to be born naturally
- if your baby is not in good health and/or is distressed
- if you have had previous major surgery or rupture of the cervix
- if you have untreated pelvic inflammatory disease (an infection in the womb, ovaries, tubes and/or cervix)
- if the placenta is obstructing the birth canal
- if you have or have had any unexplained vaginal bleeding during this pregnancy
- if you have had previous womb surgery including a previous Caesarean birth for any previous babies
- if you are hypersensitive (allergic) to dinoprostone or any of the other ingredients of PROPESS (listed in section 6).

The doctor or nurse will not give you PROPESS or will remove it after it has been given to you:

- once labour starts
- if you need to be given a drug e.g. oxytocic to help your labour progress
- if your contractions are too strong or prolonged
- if your baby becomes distressed
- if you get side effects (see 4. Possible side effects).

There is limited experience of using PROPESS if your waters have been broken. Your doctor or nurse will remove PROPESS after it has been given to you if your waters break or are going to be broken by the doctor or nurse.

Warnings and precautions

Before you are given PROPESS, please inform your doctor or nurse if any of the following apply to you:

- if you have or have ever had asthma (breathing difficulty) or glaucoma (an eye condition)
- if you have suffered from contractions that were too strong or prolonged in a previous pregnancy
- if you have lung, liver or kidney disease
- if you are having more than one baby
- if you have had more than three full term deliveries
- if you are taking a medicine for pain and/or inflammation, containing non-steroidal anti-inflammatory drugs (also known as NSAIDs) e.g. aspirin
- if you are aged 35 or over, if you have had complications during pregnancy, such as diabetes, high blood pressure and low level of thyroid hormones (hypothyroidism), or if the pregnancy is above 40 weeks because of the increased risk of developing disseminated intravascular coagulation (DIC), a rare condition which affects blood clotting.

Children and adolescents

The use of PROPESS in children and adolescents less than 18 years has not been investigated.

Other medicines and PROPESS

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

PROPESS can make you more sensitive to medicines belonging to the class of oxytocic drugs which is used to strengthen contractions. It is not recommended to administrate these medicines together with PROPESS

Pregnancy and breast-feeding

PROPESS is used to help starting the birth process at term. PROPESS should not be used at any other time during pregnancy. The use of PROPESS during breast-feeding has not been investigated. PROPESS may be excreted in breastmilk but the amount and duration is expected to be limited and should not hinder breastfeeding. No effects on the breastfed newborns have been observed.

Driving and using machines

Not relevant as PROPESS is to be used in connection with delivery only.

3. How you are given PROPESS

The doctor or nurse will place one vaginal delivery system next to the cervix in your vagina. You should not do this yourself. Your doctor or nurse will coat the vaginal delivery system with a small amount of lubricating jelly before putting it in place. Sufficient tape will be left outside the vagina, to facilitate the removal of the vaginal delivery system when needed.

You should be lying down during this procedure and you will have to stay that way for about 20-30 minutes after insertion of PROPESS.

When placed in position, the vaginal delivery system takes up some of the moisture there. This allows the dinoprostone to slowly being released.

Whilst the vaginal delivery system is in place helping to start your labour, you will be examined regularly amongst other things for:

- opening of your cervix
- uterine contractions
- labour pains and the continuing health of your baby

The doctor or nurse will decide how long PROPESS needs to be kept in place, depending on your progress. PROPESS can be left in place for a maximum of 24 hours.

On removal of the product from the vagina the vaginal delivery system will have swollen to 2-3 times of its original size and be pliable.

If you have been given PROPESS for a longer time than you should

If you have been given PROPESS for a longer time than you should it may lead to increased contractions or the baby may become distressed. The PROPESS vaginal delivery system will then be taken out immediately.

4. Possible side effects

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

Common: may affect up to 1 in 10 people

- Increased contractions of the womb which may or may not affect the baby.
- The baby may become distressed and/or its heart rate could become faster or slower than normal.
- Discoloured amniotic fluid

Uncommon: may affect up to 1 in 100 people

- Headache
- Decrease in blood pressure
- The newborn baby has difficulty breathing immediately after birth
- The newborn baby has high blood levels of bilirubin, a breakdown product of red blood cells, which can cause yellowing of the skin and eyes.
- Itching
- Heavy vaginal bleeding following delivery
- The placenta detaches from the wall of the womb before the baby is delivered
- Overall newborn condition depressed immediately after birth
- Slow progress in the birth process
- Inflammation of the membranes that are lining the inside of the womb
- The mother's uterus does not shrink after delivery due to lack of normal uterine contractions
- Feeling of burning in the genital area
- Fever

Not known: frequency cannot be estimated from the available data

- Disseminated Intravascular Coagulation (DIC), a rare condition which affects blood clotting. This can cause blood clots to form and may increase the risk of bleeding.
- The fluid that surrounds the baby during pregnancy can enter the mother's bloodstream during delivery and block a blood vessel leading to a condition called anaphylactoid syndrome of pregnancy, which could include, symptoms such as: shortness of breath, low blood pressure, anxiety and chills; life-threatening problems with blood clotting, seizures, coma, bleeding and fluid in the lungs and fetal distress such as a slow heartrate.
- Hypersensitivity reaction and severe allergic reactions (anaphylactic reaction), which

can include: difficult breathing, shortness of breath, weak or rapid pulse, dizziness, itching, redness of skin and rash.

- Abdominal pain
- Nausea
- Vomiting
- Diarrhea
- Swelling of the genital area
- Tearing of the womb

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any side effects not listed in this leaflet. You can also report side effects directly via <the national reporting system> <[to be completed nationally]>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store PROPESS

Keep this medicine out of the sight and reach of children.

Do not use PROPESS after the expiry date which is stated on the foil sachet and the carton.

Store in a freezer (-10 to -25°C). Store in the original container in order to protect from moisture.

Medicines should not be disposed via wastewater or household waste. After usage, your doctor or nurse will dispose the whole product as clinical waste. These measures will help to protect the environment.

6. Contents of the pack and other information

What PROPESS contains

- The active substance is dinoprostone, more commonly known as Prostaglandin E₂. Each vaginal delivery system contains 10 mg of dinoprostone which is released at approximately 0.3 mg per hour over 24 hours.
- The other ingredients are crosslinked macrogol (hydrogel) and polyester yarn.

What PROPESS looks like and contents of the pack

The vaginal delivery system is a small rectangular shaped piece of plastic contained in a knitted retrieval system. The plastic piece is a hydrogel polymer which swells in the presence of moisture to release dinoprostone. The retrieval system has a long tape which allows the doctor or nurse to remove it when they need to.

Each vaginal delivery system is contained within an individual sealed foil sachet produced from an aluminium/polyethylene foil laminate strip and packed in a carton.

Pack containing 5 vaginal delivery systems.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

Ferring GmbH
Wittland 11
24109 Kiel

Germany

Ferring Controlled Therapeutics Ltd (FCT)
1 Redwood Place
Peel Park Campus
East Kilbride, G74 5PB,
Scotland, United Kingdom

<This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, PROPESS 10 mg vaginales Freisetzungssystem
Belgium, PROPESS 10 mg hulpmiddel voor vaginaal gebruik, PROPESS 10 mg système de diffusion vaginal, PROPESS 10 mg vaginales Wirkstofffreisetzungssystem
Bulgaria, ПРОПЕС 10 mg вагинална лекарстводоставяща система / PROPESS 10 mg vaginal delivery system
Croatia, Propess 10 mg sustav za isporuku u rodnicu
Cyprus, Propess
Czechia, CERVIDIL
Denmark, Propess, vaginalindlæg
Estonia, Propess
Finland, Propess 10 mg depotlääkevalmiste, emättimeen
France, PROPESS 10 mg, système de diffusion vaginal
Germany, PROPESS 10 mg vaginales Freisetzungssystem
Greece, PROPESS 10 mg σύστημα ενδοκολπικής χορήγησης
Hungary, Propess 10mg hüvelyben alkalmazott gyógyszerleadó rendszer
Ireland, Propess 10 mg vaginal delivery system
Italy, PROPESS 10 mg – Dispositivo vaginale
Latvia, Propess
Lithuania, Propess,
Luxembourg, PROPESS 10 mg système de diffusion vaginal
Netherlands, Propess, vaginaal toedieningssysteem 10 mg
Norway, Propess
Poland, Cervidil
Portugal, PROPESS 10 mg, Sistema de libertação vaginal
Romania, PROPESS 10 mg/24 ore sistem cu cedare vaginala
Slovakia, Cervidil 10 mg vaginálny inzert
Slovenia, Propess 10mg vaginalni dostavni sistem
Spain, PROPESS 10 mg sistema de liberación vaginal
Sweden, Propess 10 mg vaginalinlägg
United Kingdom, PROPESS 10 mg vaginal delivery system>

This leaflet was last revised in 28 February 2020.

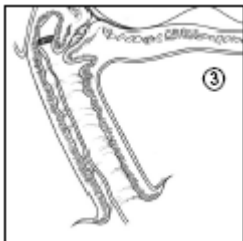
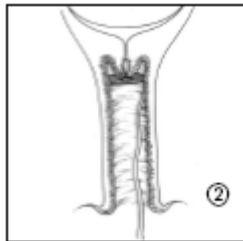
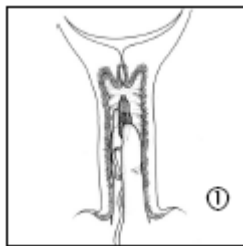
<[To be completed nationally]>

The following information is intended for medical or healthcare professionals only:

USER INSTRUCTIONS

Application

1. To remove PROPESS from the packaging, first tear the foil along the top of the sachet. Do not use scissors or sharp implements to cut the foil as this may damage the product. Use the retrieval system to gently pull the product out of the sachet. Hold the vaginal delivery system between the index and the middle finger and insert it in the vagina. If required, a small amount of water-soluble lubricant can be used.
2. PROPESS is placed crosswise high up in the rear fornix of the vagina.
3. Leave a part of the tape (app. 2 cm) hanging out of the vagina to ensure easy removal of the vaginal delivery system. The tape can be cut shorter if needed.
4. Ensure that the patient is lying down or seated for 20-30 minutes after insertion to let the vaginal delivery system swell.



Removal

PROPESS can be removed quickly and easily by carefully pulling the tape. After removal, ensure that the entire product (vaginal delivery system and retrieval system) has been removed from the vagina.