PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPESS® 10 mg vaginal delivery system

Dinoprostone (prostaglandin E_2)

Sugar free

Read all of this leaflet carefully before you are given PROPESS®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist or other healthcare provider.
- PROPESS® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What PROPESS® is and what it is used for

The active ingredient in PROPESS® is dinoprostone, more commonly known as Prostaglandin E_2 (PGE_2).

PROPESS® is used to help start the birth process after 37 weeks of pregnancy is completed. The PGE_2 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 to start this process. Ask your doctor if you would like to know more.

2. What you need to know before you use PROPESS®

PROPESS® should not be administered to you:

- if you are hypersensitive (allergic) to dinoprostone (PGE_2) or any of the other ingredients of PROPESS®
- if the size of your baby's head means there may be a 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 earlier babies

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 medicine such as an 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 Possible Side Effects) such as nausea, vomiting, hypotension or tachycardia

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

Special care should be taken with PROPESS®

- 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.

After PROPESS® is inserted the uterine activity and the condition of the baby will be carefully and regularly monitored by a trained healthcare professional in a hospital or clinic where facilities for monitoring you and your baby are available (see section 3 “How to use PROPESS®”).

Children and adolescents

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

Other medicines and PROPESS®

Always tell your healthcare provider if you are taking any other medicine (This includes all complementary or traditional medicines.)

PROPESS® can make you more sensitive to medicines belonging to a class called oxytocic medicines which

are used to strengthen contractions. It is not recommended to administrate these medicines together.

Pregnancy, breastfeeding and fertility

Pregnancy

PROPESS® is used to help start the birth process. Thus, PROPESS® should not be used before 37 weeks of pregnancy is completed.

Breastfeeding

PROPESS® may be excreted in breastmilk but the amount and duration are expected to be limited and should not hinder breastfeeding.

No effects on the breastfed newborn have been observed.

Driving and using machinery:

There is no information on the effects of PROPESS® on the ability to drive and use machines.

3. How to use PROPESS®

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself PROPESS®. PROPESS® will be given to you by a trained healthcare professional in a hospital or clinic where facilities for monitoring you and your baby are available.

The doctor or nurse will place one vaginal insert next to the cervix in your vagina. You should not do this yourself. Your doctor or nurse will coat the vaginal insert with a small amount of lubricating jelly before putting it in place. Sufficient tape will be left outside the vagina, so that the vaginal insert can easily be pulled out when it is time to remove it.

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 (PGE2) to be slowly 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

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.

The doctor or nurse will decide how long PROPESS® needs to be kept in place. Do not stop treatment early by removing the product from the vagina. PROPESS® can be left in place for a maximum of 24 hours.
Only one application of PROPESS® is recommended.
If you have the impression that the effect of PROPESS® is too strong or too weak, tell your doctor or pharmacist.

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

Since a healthcare provider will administer PROPESS®, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.
If you have been given PROPESS® for a longer time than you should, it may lead to increasing contractions or the baby may become distressed. The PROPESS® vaginal delivery system will then be taken out immediately.

4. Possible side effects

PROPESS® can have side effects.

Not all side effects reported for PROPESS® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving PROPESS®, please consult your healthcare provider for advice.

If any of the following happens, stop using PROPESS®, and tell your doctor immediately or go to the casualty department at your nearest hospital (***Please note:*** *PROPESS® will only be given to you in a hospital by a qualified healthcare provider)*:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to PROPESS®. You may need urgent medical attention or hospitalisation. (***Please note:*** *PROPESS® will only be given to you in a hospital by a qualified healthcare provider.)*

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- The baby may become distressed and/or its heart rate could become faster or slower than normal.
- Changes in the way your heart beats, for example, if you notice it beating faster or slower.
- Increased contractions of the womb which may or may not affect the baby.
- Discoloured amniotic fluid.
- Heavy blood lost after delivery of foetus
- Anaphylactoid syndrome of pregnancy. 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 foetal distress such as a slow heartrate.

- Uterine atony. It occurs when the uterus fails to contract after the delivery of the baby, and it can lead to a potentially life-threatening condition known as postpartum haemorrhage

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Headache
- Neonatal hyperbilirubinaemia, a condition where 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.
- Low Apgar score (scoring system doctors and nurses use to assess newborns one minute and five minutes after they are born)
- Arrest labour (slow progress in the birth process)
- Chorioamnionitis. It is a condition that can affect pregnant women. In this condition, bacteria infect the chorion and amnion (the membranes that surround the foetus) and the amniotic fluid (in which the foetus floats). This can lead to infections in both the mother and foetus
- Vulvovaginal burning sensation (burning sensation around the vaginal area)
- Febrile disorder (unexplained fever)

The following side effects have been seen after the product was marketed. Frequency is not known (cannot be estimated from the available data):

- Foetal death, stillbirth and death of the newborn baby (neonatal death); especially following serious

events such as tearing of the womb.

- Disseminated Intravascular Coagulation (DIC), a condition which affects blood clotting. This can cause blood clots to form and may increase the risk of bleeding.
- Abdominal pain (stomach pain)
- Nausea (feeling sick)
- Vomiting (being sick)
- Diarrhoea
- Genital oedema (swelling of the genitals due to build-up of fluid in the soft tissues of the genitals)
- Rupture of the uterus

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PROPESS®.

5. How to store PROPESS®

- Store unopened in a deep-freezer (between -10 °C and -25 °C).
- Store in the original container in order to protect from moisture.
- No thawing is required prior to use.
- The product is not stable when stored at room temperature.
- Store all medicines out of reach of children
- Do not use PROPESS® after the expiry date which is stated on the sachets and carton.
- Return all unused medicine to your pharmacist.

- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PROPESS® contains

The active substance is dinoprostone, more commonly known as Prostaglandin E2. There is 10 mg of dinoprostone in each vaginal delivery system 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

PROPESS® 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.

PROPESS® vaginal delivery system is presented in individual sealed aluminium/polyethylene laminated sachets in packs containing 5 vaginal inserts.

Holder of Certificate of Registration

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Namibia Registration Number (s):

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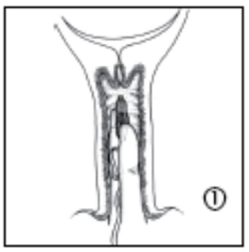
The following information is intended for medical or healthcare professionals only:

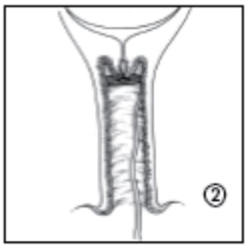
USER INSTRUCTIONS

Application

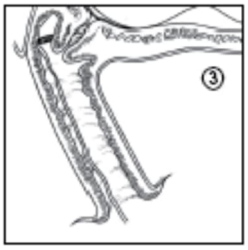
1. To remove PROPESS® from the packaging, first tear the foil along the top of the sachet. Do not use scissors or sharp implements to cut the foil as this may damage the product. Use the retrieval system to gently pull the product out of the sachet. Hold the vaginal insert between the index and the middle 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 (approx. 2 cm) hanging out of the vagina to ensure easy removal of the vaginal insert. 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 insert swell.

Removal

PROPESS® can be removed quickly and easily by carefully pulling the tape.

After removal, ensure that the entire product (vaginal insert and retrieval system) has been removed

from the vagina.