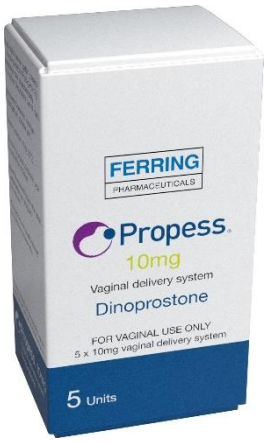
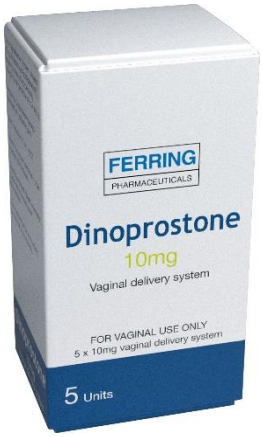
IMPORTANT INFORMATION: PROPESS® (dinoprostone) upcoming name/code change

Dear Healthcare Professional,

From December 2024, Ferring Pharmaceuticals will be removing the brand name PROPESS® (dinoprostone) from our 10 mg vaginal delivery system. The product will be sold under its generic name, dinoprostone, from December 2024.

We want to assure you that this change will not impact the quality or efficacy of our product, as the manufacturing process will remain the same. There are no alterations to the package size and any modifications to the packages' look and feel are minimal, as you can see below. However, please note there is a new PIP code.

Product Names	Pack Image	PIP Code	Date
Previous: **PROPESS®** 10mg vaginal delivery system		**06095640**	**End:** November 2024
New: **Dinoprostone** 10mg vaginal delivery system		**1277755**	**Start**: December 2024

We kindly request that once the new product becomes available, you promptly place an order using the new PIP Code. This will ensure that there are no delays or issues in dispensing this product to your patients.

If you require any further information or assistance with updating your system, please do not hesitate to contact us.

Thank you for your understanding and attention to this matter.

Sincerely,

Mel Foster-Hawes
General Manager Ferring UK & Ireland

Commercial-related questions should be directed to:
Ferring Customer Services
0800 1114125
Customer.services@ferring.com

Medical related questions should be directed to:
Ferring Medical
0800 1114126
Medical.uk@ferring.com

Prescribing Information: Dinoprostone 10mg vaginal delivery system. Please consult the full Summary of Product Characteristics before prescribing.

Name of Product: Dinoprostone 10mg vaginal delivery system. **Composition:** Each system contains 10mg dinoprostone (Prostaglandin E2) and releases 0.3mg/hour dinoprostone over 24 hours. **Indications:** Initiation of cervical ripening in adult patients, at term (from 37 completed weeks of gestation). **Posology and administration:** Should only be administered by qualified healthcare personnel in hospitals/clinics with specialised obstetric units with facilities for continuous fetal and uterine monitoring. After insertion, uterine activity and fetal condition must be carefully and regularly monitored. Administer one vaginal delivery system high into the posterior vaginal fornix. **Remove Dinoprostone:** when cervical ripening is complete, at onset of labour (presence of regular painful uterine contractions every 3 minutes irrespective of cervical change), spontaneous rupture of membranes/amniotomy, any suggestion of uterine hyper stimulation/hypertonic uterine contractions, evidence of fetal distress, evidence of maternal systemic adverse dinoprostone effects e.g. nausea, vomiting, hypotension, tachycardia, at least 30 minutes before starting oxytocin. Remove the vaginal delivery system after 24 hours irrespective of whether cervical ripening has been achieved. A dosing interval of at least 30 minutes is recommended for the sequential use of oxytocin following the removal of the vaginal delivery system. Only one application of dinoprostone is recommended. **Contraindications:** Dinoprostone should not be used or left in place: when labour has started, when oxytocic drugs and/or other labour induction agents are being given, when strong prolonged contractions would be inappropriate, e.g. previous major uterine/cervix surgery or uterine cervix rupture, cephalopelvic disproportion, fetal malpresentation, suspicion/evidence of fetal distress, current pelvic inflammatory disease (unless adequately treated), hypersensitivity to dinoprostone or excipients, or placenta praevia or unexplained vaginal bleeding during current pregnancy. **Use in pregnancy:** Do not use prior to 37 completed weeks of gestation. **Use in lactation:** No effects on breastfed new-borns have been observed in studies. **Special Warnings and Precautions:** Assess condition of cervix carefully before using dinoprostone. After insertion, regularly and carefully monitor uterine activity and fetal condition. Must only be used in hospitals/clinics with specialised obstetric units with facilities for continuous fetal and uterine monitoring If any suggestion of maternal/fetal complications or if adverse effects occur, remove the vaginal delivery system. Uterine rupture has been reported in association with the use of dinoprostone, mainly in patients with contra-indicated conditions. Therefore, do not administer dinoprostone to patients with a history of previous caesarean section or uterine surgery. If uterine contractions are prolonged or excessive, remove the vaginal delivery system immediately due to possibility of uterine hypertonus or rupture. Use dinoprostone with caution in patients with ruptured membranes, a previous history of uterine hypertonus, glaucoma or asthma. Stop medication with non-steroidal anti- inflammatory drugs, including acetylsalicylic acid, before administering dinoprostone. Use with caution in multiple pregnancies, when a woman has had more than three full term deliveries. A second dose of dinoprostone is not recommended. Not recommended in patients with diseases which could affect the metabolism or excretion of dinoprostone e.g., lung/liver/renal disease. Use dinoprostone with caution in women aged 35 or over, women with complications during pregnancy e.g., gestational diabetes, arterial hypertension and hypothyroidism, and women at gestational age above 40 weeks as they have a higher post-partum risk of developing disseminated intravascular coagulation (DIC). These factors may additionally enhance the risk of DIC in women with pharmacologically induced labour. Therefore, uterotonic drugs, such as dinoprostone should be used with caution in these women. In the immediate post- partum phase, the physician should carefully monitor for early signs of a developing DIC (e.g. fibrinolysis). Use of dinoprostone may result in inadvertent placental abruption and subsequent embolisation of antigenic tissue rarely causing Anaphylactoid Syndrome of Pregnancy (Amniotic Fluid Embolism). **Interactions:** Prostaglandins potentiate uterotonic effect of oxytocic drugs. Do not use dinoprostone concurrently with oxytocic drugs. **Side Effects:** Common and serious uncommon/frequency not known adverse reactions are reported here. Please consult the Summary of Product Characteristics for full information. Common: fetal heart rate disorder, abnormal labour affecting fetus, abnormal uterine contractions, uterine tachysytole, uterine hyperstimulation, uterine hypertonus, meconium in amniotic fluid. Uncommon serious: hypotension, neonatal respiratory distress related conditions, neonatal hyperbilirubinaemia, postpartum haemorrhage, premature separation of placenta, low Apgar score, chorioamnionitis, uterine atony. Frequency not known serious: disseminated intravascular coagulation, anaphylactic reaction, hypersensitivity, anaphylactoid syndrome of pregnancy, fetal distress syndrome, fetal death, stillbirth, neonatal death, uterine rupture. **Marketing Authorisation Number:** 03194/0084. **Marketing Authorisation Holder:** Ferring Pharmaceuticals Ltd, Drayton Hall, Church Road, West Drayton, UB7 7PS. **Legal Category:** POM. **Basic NHS Price:** £165 for 5 x 10mg vaginal delivery systems. **Date of Preparation of Prescribing Information:** October 2023 **UK-PS-2300015**

Adverse events should be reported. Reporting forms and information can be found at

www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to Ferring Pharmaceuticals Ltd.

Tel: 0800 111 4126. Email : **medical.uk@ferring.com**