Prescribing Information: Propess® 10mg vaginal delivery system

Please consult the full Summary of Product Characteristics before prescribing. Name of Product: Propess® 10mg vaginal delivery system.
Composition: Each vaginal delivery system contains 10mg dinoprostone (Prostaglandin E_2).
Indications: Initiation of cervical ripening in patients, at term (from 38th week of gestation).
Dosage: One vaginal delivery system administered high into the posterior vaginal fornix. If there has been insufficient vaginal ripening in 24 hours, the vaginal delivery system should be removed. A dosing interval of at least 30 minutes is recommended for the sequential use of oxytocin following the removal of the vaginal delivery system.
Contraindications: Propess® should not be used or left in place: when labour has started, when oxytocic drugs are being given, when strong prolonged contractions would be inappropriate, when there is current pelvic inflammatory disease (unless adequate prior treatment has been instituted), when there is hypersensitivity to dinoprostone or any of the excipients or when there is placenta praevia or unexplained vaginal bleeding during the current pregnancy. **Use in pregnancy:** Only to be used at term when labour induction is indicated. **Use in lactation:** Not indicated.
Special Warnings and Precautions: Condition of the cervix should be assessed carefully before Propess® is used. After insertion, uterine activity and fetal condition must be monitored regularly. If there is any suggestion of maternal or fetal complications or if adverse effects occur, the vaginal delivery system should be removed from the vagina. Propess® should be used with caution in patients with ruptured membranes, a previous history of uterine hypertony, glaucoma or asthma. Medication with non-steroidal anti-inflammatory drugs, including acetylsalicylic acid, should be stopped before administration of dinoprostone. If uterine contractions are prolonged or excessive, there is possibility of uterine hypertonus or rupture and the vaginal delivery system should be removed immediately. Propess® should not be administered to patients with a history of previous caesarean section or uterine surgery given the potential risk for uterine rupture and associated obstetrical complications. Use with caution in multiple pregnancies. A second dose of Propess® is not recommended. Not recommended in patients with diseases which could affect the metabolism or excretion of dinoprostone. Propess® should be used with caution in women aged 35 or over, women with complications during pregnancy such as diabetes mellitus, 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. **Side Effects:** Occasional side effects include CTG changes, unspecified fetal distress and increased uterine activity with hypertonic contractions with or without fetal distress. There is a much greater risk of hyperstimulation if the dinoprostone source is not removed before administration of oxytocin. Commonly reported adverse events are – abnormal labour affecting the fetus, fetal heart rate disorder, fetal distress syndrome and uterine hypertonus. Gastrointestinal effects such as nausea, vomiting and diarrhoea have been reported. Uterine rupture and disseminated intravascular coagulation have reported rarely. Please consult the full Summary of Product Characteristics for further information about side effects.
Nature and Contents of Container: Packs containing 5 vaginal delivery systems. Vaginal delivery systems are packed in individual sachets.
Special Precautions for Storage: Store in a freezer in the original container.
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 inserts.
Date of Preparation of Prescribing Information: December 2018
PS/223/2010/UK(5).

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**