This information was up to date at the time of release to the Heads of Midwifery.
The editorial board does not accept liability for any errors or omissions following its subsequent publication.
Updating arrangements for the formulary should be decided upon and implemented at a local level.

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

Dinoprostone (Propess®) **(PGD)**

Legal status (GSL, P or POM on exemption list, or PGD)	▪ POM - Midwife may supply/administer in accordance with a PGD.
Clinical indication:	Induction of labour for post maturity in accordance with local guideline
Inclusion criteria:	Patients requiring induction of labour for post maturity – see local guideline
Exclusion criteria:	It should not be used: • when labour has started • when oxytocic drugs are being given • when strong prolonged uterine contractions would be inappropriate such as in patients o who have had previous major uterine surgery, eg caesarean section, myomectomy etc o with cephalopelvic disproportion/high free head o with fetal malpresentation o with suspicion or evidence of fetal distress o who have had more than three full term deliveries o rupture of the cervix • when there is current pelvic inflammatory disease, unless adequate prior treatment has been instituted • when there is hypersensitivity to dinoprostone or to any of the excipients • when there is placenta previa or significant unexplained vaginal bleeding during the current pregnancy • patients with ruptured membranes • active cardiac, pulmonary, renal or hepatic disease.
Potential adverse reactions:	Propess® should be removed and the patient referred to delivery suite in the following situations • regular contractions (≥ 3 in 10) • BS ≥ 7 • there is a evidence of uterine tachysystole, hypertonus or hyperstimulation o tachysystole = ≥ 5 contractions in 10 minutes with normal CTG o hypertonus = painful contraction lasting ≥ 90 seconds: normal CTG o hyperstimulation = tachysystole or hypertonus with abnormal CTG • concern about the fetal heart rate/abnormal CTG • vaginal bleeding • there is evidence of maternal systemic adverse effect such as severe nausea and vomiting, hypotension or tachycardia

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Cautions/Need for further advice/Circumstances when further advice should be sought from the doctor:	Caution should be exercised in the administration of dinoprostone for the induction of labour in patients with: ▪ asthma or a history of asthma ▪ epilepsy or a history of epilepsy ▪ glaucoma or raised intra-ocular pressure ▪ compromised cardiovascular, hepatic, or renal or lung function ▪ hypertension ▪ previous history of uterine hypertony ▪ multiple pregnancy ▪ if a caution applies, with the exception of age and length of gestation, consultation with a doctor is required before administration or supply ▪ document consultation in maternity record
Action if patient declines or is excluded:	▪ refer to authorised prescriber or doctor ▪ document in maternity record
Referral arrangements for further advice/cautions:	In accordance with local guidelines.
Medicine Details	
Name, form & strength of medicine:	Vaginal delivery system containing 10mg dinoprostone (Prostaglandin E_2) dispersed throughout its matrix.
Route/Method of administration:	For vaginal administration into the posterior fornix.
Dosage (include maximum dose if appropriate):	10mg
Frequency:	One dose only to be removed after 24 hours if not sooner- see monitoring and follow up section.
Duration of treatment:	Max 24 hours
Maximum or minimum treatment period:	Max 24 hours
Quantity to supply/administer:	10mg, one dose only to be removed after 24 hours if not sooner- see monitoring and follow up section.
▼Black Triangle Drug:*	No

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Is the use outwith the SPC:**	Outpatient use is outwith the SPC
Storage requirements and product details	Store in freezer. If discovered that it has not been stored in freezer, replace in freezer marked "do not use awaiting information on suitability for use". Determine the maximum period of time stored at room or fridge temperature and then contact pharmacy for further advice.
*The black triangle symbol (▼) identifies newly licensed medicines that are monitored intensively by the MHRA/CSM ** Summary of Product Characteristics	
Warnings including possible adverse reactions and management of these:	▪ *Potentiates the effect of oxytocin and Syntometrine® if used in sequence, the patient's uterine activity should be carefully monitored.* ▪ *NSAIDs including aspirin inhibit action.* ▪ *Consult current BNF appendix 1 for most up to date list.* ▪ *If there is a drug interaction, consult with a doctor before administration.* ▪ *Patients aged 35 and over, patients with complications during pregnancy, such as gestational diabetes, arterial hypertension and hypothyroidism, and patients at gestational age above 40 weeks have a higher post-partum risk for developing disseminated intravascular coagulation (DIC). These factors may additionally enhance the risk of disseminated intravascular coagulation in patients with pharmacologically induced labour. Therefore, dinoprostone and oxytocin should be used with caution in these patients. In the immediate post-partum phase look out carefully for early signs of a developing DIC (eg fibrinolysis).* ▪ *Nausea, vomiting and diarrhoea are most commonly reported. Other side effects include pulmonary and amniotic fluid embolism, hypertension, bronchospasm/asthma, rash, fever, backache. Vaginal symptoms of warmth, irritation and pain. Rarely hypersensitivity reactions including anaphylaxis, uterine rupture and cardiac arrest and disseminated intravascular coagulation.* ▪ *on labour - uterine hypercontractility or hypotonus, uterine hyperstimulation, abruption placentae, rapid cervical dilation* ▪ *on the neonate - fetal bradycardia /fetal distress, low Apgar scores, stillbirth, neonatal death* ▪ *on breast feeding - no hazard at recommended dose*
Medicine interactions and action that will be taken if a patient is taking a medicine that may interact	None of note.
Overdose information:	▪ Symptoms of overdose are uterine hyper stimulation, hypertonus, fetal distress. ▪ Remove device immediately and follow local protocol for hyper-stimulation. ▪ In the event of overdose for further advice contact the National Poisons Centre for advice. Tel 0344 892 0111

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Advice to patient/carer including written information provided:	Patient should remain recumbent for at least 30 minutes after administration. A patient information leaflet will be given to the patient, which will include instruction on how and when to remove the device.
	A CTG should be performed according to local guidelines. Low risk patients may go home; additional information will be required. See local guideline.
Follow up:	Once labour established or SRM monitor uterine activity and fetal condition regularly.

References

- Summary of Product Characteristics Propess® Pessary text revision 12.2018. Accessed 31.12.2019 http://www.medicines.org.uk

- http://www.bnf.org