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 Vaginal gel (Prostin E2®) **(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 in accordance with local guideline.
Inclusion criteria:	Patients requiring induction of labour.
Exclusion criteria:	Sensitivity to prostaglandins or constituents of vaginal gel. Do not use where labour has started. Dinoprostone should not be given in the following circumstances: for patients in whom oxytocic drugs are generally contra-indicated such as o previous caesarean section or major uterine surgery o cephalopelvic disproportion/high free head o fetal malpresentation is present o clinical suspicion or definite evidence of pre-existing fetal distress o history of difficult labour and/or traumatic delivery o grand multiparae. See local guideline. patients with ruptured membranes past history of, or existing, pelvic inflammatory disease, unless adequate prior treatment has been instituted clinical suspicion or definite evidence of placenta praevia or significant unexplained vaginal bleeding during this pregnancy active cardiac, pulmonary, renal or hepatic disease.

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Potential adverse reactions	▪ *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 patient with pharmacologically induced labour. Dinoprostone should therefore be used with caution in these patients.* *In the immediate post-partum phase look out carefully for early signs of a developing DIC (e.g. 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, uterine rupture, cardiac arrest and postpartum DIC.* ▪ *on labour - uterine hypercontractility or hypertonus, Uterine rupture, placental abruption, rapid cervical dilation, pulmonary amniotic embolism* ▪ *on the neonate - fetal bradycardia /fetal distress, low Apgar scores, stillbirth, neonatal death* ▪ *on breast feeding- no hazard at recommended dose*
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 function ▪ hypertension ▪ uterine hypertony ▪ multiple pregnancy ▪ if a caution applies 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:	Refer to an obstetrician if a third dose is required.
Medicine Details	

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Pharmacology	Dinoprostone is the same as the naturally occurring prostaglandin E_2 that is found in most tissue and has many actions. It is involved in the cervical ripening and activates the enzyme collagenase causing the cervix to soften. It also causes contraction of the smooth muscle of the uterus, vasodilation and bronchodilation. It has a very short half-life of 1-3 minutes and is rapidly metabolised in lungs, kidney, liver and spleen. Prostin E2® peak plasma levels occur about 90 minutes after vaginal gel administration and absorption is variable.
Name, form & strength of medicine:	Dinoprostone vaginal gel 1 mg and 2 mg.
Route/Method of administration:	For vaginal administration high into the posterior fornix (avoiding administration into the cervical canal).
Dosage (include maximum dose if appropriate):	**Primigravida patients** with unfavourable induction features (Bishop score of 4 or less) an initial dose of 2 mg should be administered vaginally. **In other patients** an initial dose of 1 mg should be administered vaginally. **In both groups of patients,** a second dose of 1 mg or 2 mg may be administered after 6 hours as follows: 1 mg should be used where uterine activity is insufficient for satisfactory progress of labour. 2 mg may be used where response to the initial dose has been minimal. Maximum dose 4 mg in unfavourable primigravida patients or 3 mg in other patients.
Frequency:	One dose to be inserted high into the posterior fornix. A second dose may be inserted after six hours if labour is not established. Maximum dose – see above.
Duration of treatment:	N/A
Maximum or minimum treatment period:	A second dose may be administered after six hours if labour is not established – (see above). The midwife may administer a maximum of only two doses.
Quantity to supply/administer:	1 application of vaginal gel
▼Black Triangle Drug:*	No
Is the use outwith the SPC:**	No
Storage requirements and product details	Store in refrigerator 2-8 C.
*The black triangle symbol (▼) identifies newly licensed medicines that are monitored intensively by the MHRA/CSM ** Summary of Product Characteristics	

Dinoprostone Vaginal Gel (Prostin E2®) **(PGD)**	
Warnings including possible adverse reactions and management of these:	*Prostin E2 Vaginal Gel and Vaginal Tablets are not bioequivalent.* *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.* *Document consultation in maternity record.*
Overdose	▪ Symptoms of overdose are uterine hyper-stimulation and hypertonus, fetal distress. ▪ 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
Advice to patient/carer including written information provided:	A manufacturer's patient information leaflet should be available if requested by patient.
Monitoring (if applicable):	Patient should remain recumbent for at least 30 minutes after administration. A CTG should be performed. Low risk women may go home if local guideline permits. Once labour established or SRM, monitor uterine activity and fetal condition regularly. Refer to an obstetrician if uterine activity is insufficient for satisfactory progress of labour.
Follow up:	Once labour established or SRM monitor uterine activity and fetal condition regularly.

References

1. Summary of Product Characteristics http://www.medicines.org.uk for Prostin E2 Vaginal Gel 1 mg and 2 mg (text last revised February 2018) accessed 22/12/2019

2. http://www.bnf.org