

<b>Areas where applicable</b>	Maternity inpatient services – according to local guidelines
<b>Authorised Prescribers</b>	<p>Prescribing is restricted to:</p> <ul style="list-style-type: none"> <li>• A specialist who is either a <i>Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists</i> or a <i>Fellow of the Royal College of Obstetricians and Gynaecologists</i>. The prescription must be endorsed with the individual authority reference number issued by the Pharmaceutical services Unit.</li> </ul> <p><b><u>OR</u></b></p> <ul style="list-style-type: none"> <li>• A registrar in obstetrics who has undertaken training in the administration and prescribing of dinoprostone and received written permission from the Director of Obstetrics to prescribe dinoprostone. This will be in accordance with a written protocol. The Director of Obstetrics in each facility will be responsible for providing pharmacy with a list of named approved registrars in February and August of each year.</li> </ul>
<b>Indication for use</b>	Cervical ripening at term as part of an induction of labour protocol. Individual cases should be discussed with a senior obstetrician and in conjunction with local guidelines (see reference list).
<b>Clinical condition</b>	<p>Each case must be assessed on an individual basis with consultation with an experienced/ suitably qualified Obstetrician. Dinoprostone is used in conjunction with a calculated modified Bishop's score. Mechanical methods may also be used as required.</p> <p>Local guidelines provide specifics in regards to inclusion criteria and clinical investigations prior to and during the administration.</p>
<b>Contra-indications</b>	<p>Some examples are below- this is <u>not</u> an exhaustive list:</p> <ul style="list-style-type: none"> <li>• Known hypersensitivity to dinoprostone.</li> <li>• Prior uterine surgery</li> <li>• Fetal distress</li> <li>• Vaginal bleeding</li> </ul> <p><i>A comprehensive list can be located in local guidelines.</i></p>
<b>Precautions</b>	<ul style="list-style-type: none"> <li>• Asthma ,COPD</li> <li>• Epilepsy</li> <li>• Cardiovascular disease</li> <li>• Raised intraocular pressure</li> <li>• Renal or Hepatic impairment</li> </ul>
<b>Place in Therapy</b>	First line pharmacological therapy for cervical ripening as part of an induction of labour protocol

<p><b>Dosage</b></p>	<p><b>Dinoprostone (Prostin®) gel</b></p> <ul style="list-style-type: none"> <li>• <u>Initial dose</u> (recommended):                      Nulliparous woman - 2 mg PV                      Multiparous woman - 1 mg or 2 mg PV                      (as directed by an experienced obstetrician)</li> <li>• <u>Repeat dose</u> if labour is not established after 6 hours</li> <li>• Maximum dose is 3mg in a 12 hour period</li> </ul> <p><b>Dinoprostone (Cervidil®) pessary</b>                      Single dose of dinoprostone pessary (Cervidil®) 10 mg PV                      (releases approximately 0.3 mg dinoprostone per hour over 12 hours)</p>
<p><b>Duration of therapy</b></p>	<p>If contractions do not commence, reassess the cervical (Modified Bishop's) score</p> <ul style="list-style-type: none"> <li>• Dinoprostone (Prostin®) gel - 6 hours after insertion</li> <li>• Dinoprostone (Cervidil®) pessary- 12 hours after insertion</li> </ul>
<p><b>Important Drug Interactions</b></p>	<p>Concurrent use with other oxytocic agents is not recommended</p>
<p><b>Administration instructions</b></p>	<p><b>Dinoprostone (Prostin®) gel</b></p> <ul style="list-style-type: none"> <li>• Remove gel from refrigeration and stand at room temperature for at least 30 minutes prior to use</li> <li>• Use minimal water soluble lubricants only</li> <li>• Insert dose into the posterior fornix of the vagina avoiding the cervix</li> <li>• Advise the woman to remain in bed for up to one hour to facilitate absorption</li> </ul> <p><b>Dinoprostone (Cervidil®) pessary</b></p> <ul style="list-style-type: none"> <li>• Remove from freezer immediately prior to use. Warming is not required</li> <li>• Use minimal water soluble lubricants only</li> <li>• Insert into the posterior fornix of the vagina in transverse position</li> <li>• Ensure sufficient tape outside vagina to allow removal</li> <li>• Advise the woman to remain in bed for up to one hour to facilitate absorption</li> </ul>

<p><b>Monitoring requirements</b></p> <p>Safety</p> <p>Effectiveness</p>	<ul style="list-style-type: none"> <li>Fetal welfare surveillance is required prior to, during and after the administration of dinoprostone. Refer to local guidelines.</li> <li>Maternal surveillance is required prior to, during and after the administration of dinoprostone. Refer to local guidelines.</li> </ul> <p>The risk of uterine hyperstimulation with fetal heart changes is increased (4.8% vs 1%) and the rate of caesarean section reduced by around 10% (13.5% vs 14.8%).</p> <p>Adverse drug reactions include:</p> <ul style="list-style-type: none"> <li>Uterine hyperstimulation</li> <li>Fetal distress</li> <li>Fever</li> <li>Nausea and vomiting</li> <li>Diarrhoea</li> <li>Abdominal pain</li> </ul> <p>Increased risk of postpartum disseminated intravascular coagulation (DIC)</p> <p>Onset of painful uterine contractions with cervical dilatation</p>
<p>Management of complications</p>	<p>Hypertonic uterine activity:</p> <ul style="list-style-type: none"> <li>Remove dinoprostone pessary and consider removal of any dinoprostone gel</li> <li>Notify registrar/ consultant</li> <li>Administer tocolysis as indicated</li> </ul>
<p><b>Basis of Protocol/Guideline:</b></p>	<ol style="list-style-type: none"> <li><a href="#">NSW Ministry of Health Guideline GL2014 015 - Maternity - Management of Pregnancy Beyond 41 Weeks Gestation</a></li> <li>Australian Medicines Handbook –Dinoprostone, last updated July 2021</li> <li><a href="#">MIMS Online</a>. Prostin E2 Vaginal Gel [Pfizer]. 2020 [cited 02/09/21].</li> <li><a href="#">MIMS Online</a>. Cervidil Pessary [Ferring]. 2018 [cited 02/09/2021].</li> <li>Kelly AJ, Malik S, Smith L, Kavanagh J, Thomas J. Vaginal prostaglandin (PGE2 and PGF2a) for induction of labour at term. Cochrane Database of Systematic Reviews. 2014; Issue 6. Art. No.: CD003101. DOI:10.1002/14651858.CD003101.pub3</li> <li>McDonnell R. Induction of labour <i>Obstet Gynecol</i> 2011;13[3]: 62-64</li> <li>SGH-TSH WCH CLIN068 Clinical Business Rule: Induction and Augmentation of Labour</li> <li>RHW Local Operating Procedure: Prostaglandin Administration for Cervical Preparation</li> <li>Use of prostaglandins for induction of Labour (endorsed by RANZCOG :July 2006, Current March 2019, review due March 2022)</li> </ol>
<p><b>Groups consulted in development of this guideline</b></p>	<p>Women’s and Babies Clinical Governance Committee</p> <p>Dr Sarah Clements</p> <p>Midwifery Unit Managers</p> <p>SESLHD Women’s and Children’s Stream</p> <p>RHW Pharmacy</p>

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