

**Midwife Initiated Medicine Protocol  
Nicotine Replacement Therapy (NRT)  
(July 2008 / Version 1)**

<b>Drug Formulations</b>	Nicotine Replacement Therapy (NRT) – 4 mg lozenge (Nicabate®)
<b>Areas where Protocol/Guideline applicable</b>	All units where midwives provide care to pregnant or breastfeeding patients
<b>Areas where Protocol/Guideline not applicable</b>	All units where midwives DO NOT provide care to pregnant or breastfeeding patients.
<b>Authorised Prescribers</b>	Midwife initiated for up to 24-hours, then medical officer to review and chart.
<b>Indication for use</b>	Pregnant or breastfeeding patients who smoke >10 cigarettes a day or usually smoke their first cigarette within 30 minutes of waking  <b>or</b> Pregnant or breastfeeding patients who are unable to remain abstinent prior to, and/or during their hospital admission.  Midwives <b>should not</b> administer lozenges to; <ul style="list-style-type: none"> <li>• <i>Patients who have contraindications to lozenge (refer to medical officer)</i></li> </ul> NRT <b>should not</b> be administered to: <ul style="list-style-type: none"> <li>• <i>Children under 12-years of age</i></li> </ul>
<b>Clinical condition</b>	Pregnant or breastfeeding patients who smoke >10 cigarettes a day or usually smoke their first cigarette within 30 minutes of waking  <b>or</b> Pregnant or breastfeeding patients who are unable to remain abstinent prior to, and/or during their hospital admission.
<b>Contra-indications</b>	<b>Contraindications for lozenge include:</b> <ul style="list-style-type: none"> <li>• Non tobacco users</li> <li>• Phenylketonuria or known hypersensitivity to nicotine or any component of the lozenge</li> </ul> The above contraindications apply to midwife initiated NRT only.  <b>If a patient with these contraindications continues to smoke, prompt the medical officer to consider NRT.</b>
<b>Precautions</b>	Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. If the patient has a precaution/s to NRT - provide NRT but indicate precaution/s to medical officer for review.  <b>Precautions for lozenge include:</b> <ul style="list-style-type: none"> <li>• Hepatic or severe renal insufficiency</li> <li>• Diabetes Mellitus</li> <li>• Underlying cardiovascular disease (recent myocardial</li> </ul>

	<p>infarction, severe dysrhythmia or CVA)</p> <ul style="list-style-type: none"> <li>• Allergic reactions (susceptibility to angiodema and urticaria)</li> <li>• Pheochromocytoma and uncontrolled hyperthyroidism</li> <li>• Gastrointestinal disease</li> <li>• People on a low sodium diet</li> <li>• Pregnancy &amp; lactation</li> </ul>
<p><b>Proposed Place in Therapy</b></p> <p>State whether drug to be used as first, second or third line. Where not first line, describe therapies to be used first</p>	<p>First Line: 4mg lozenge</p> <ul style="list-style-type: none"> <li>• If patient has contraindications to lozenge refer to MO for review.</li> </ul>
<p><b>Dosage</b></p> <p>(Include dosage adjustment for specific patient groups)</p>	<ul style="list-style-type: none"> <li>• 4mg Nicotine per lozenge</li> <li>• When used as single therapy, maximum 15 per day.</li> <li>• Frequency is every 30-60 minutes (self-titrate dose according to withdrawal symptoms),</li> <li>• One lozenge placed in mouth and moved side to side in mouth until dissolved (for 20-30mins).</li> <li>• Do not chew or swallow whole.</li> <li>• Do not eat or drink while lozenge is in the mouth.</li> </ul>
<p><b>Duration of therapy</b></p>	<p>When used as a single therapy, a maximum of 15 lozenges per 24 hour period.</p>
<p><b>Important Drug Interactions</b></p>	<p>No clinically relevant interactions between NRT and other drugs have been established - BUT the PI cautions that the dose of certain substances may need to be adjusted at cessation of smoking (with or without nicotine replacement therapy).</p> <p>Potential drug interactions should be assessed by a medical officer as soon as possible.</p> <ul style="list-style-type: none"> <li>• Anticonvulsants may require special monitoring and/or dose adjustment</li> <li>• Drugs that may require adjustment in dose once smoking ceases: paracetamol, caffeine, theophylline, oxazepam, oestrogens, warfarin, lignocaine, imipramine, pentazocine, tacrine, clomipramine, fluvoxamine, Adrenergic agonists (e.g. isoprenaline and phenylephrine), Adrenergic antagonists (e.g. prazosin, labetalol)</li> <li>• Some medicines to treat depression</li> <li>• Antipsychotics e.g. Clozapine, Olanzapine</li> <li>• Insulin</li> </ul>
<p><b>Administration instructions</b></p>	<p>When a nurse administers a dose of a nurse-initiated medication to a patient, the nurse must make a record in ink on the medication chart of the name of the medication, date, time, dose and any other relevant details and sign the entry. The record should be made in an appropriate section of the chart, such as an area dedicated to nurse-initiated medication or the 'stat' (once only) section.</p>

	<p>NRT should <b>not</b> be administered past a 24 hour period without a Medical Officer (MO) reviewing. If, on this review, the medication is to continue, it must be ordered on the medication chart by the MO.</p> <p><b>Use of lozenge in lactation</b></p> <p>Patient should breastfeed just prior to using lozenge to allow as much time as possible between NRT use and breastfeeding</p>
<p><b>Monitoring requirements</b></p> <p>Safety</p> <p>Effectiveness (state objective criteria)</p>	<p><b>Monitor:</b></p> <ul style="list-style-type: none"> <li>• Exacerbated symptoms in persons suffering form active oesophagitis, oral or pharyngeal inflammation or gastritis.</li> <li>• Exacerbation of extrapyramidal side effects.</li> <li>• Diabetes Mellitus- monitor BSL closely.</li> <li>• Smoking withdrawal symptoms - use Nicotine Withdrawal Monitoring Tool.</li> </ul> <p>Certain adverse symptoms reported may be related to withdrawal symptoms associated with smoking cessation.</p> <p><b>Nicotine Withdrawal Symptoms;</b></p> <ul style="list-style-type: none"> <li>• Insomnia</li> <li>• Depression</li> <li>• Irritability</li> <li>• Anxiety</li> <li>• Difficulty concentrating</li> <li>• Restlessness</li> <li>• Cravings</li> <li>• Decreased heart rate</li> <li>• Increased appetite or weight gain</li> <li>• Frustration or anger</li> <li>• Sleeplessness</li> </ul> <p><b>Possible adverse reactions to lozenge:</b></p> <ul style="list-style-type: none"> <li>• Gastrointestinal upset (including nausea, hiccups and flatulence) and indigestion</li> <li>• Mouth irritation and throat burning</li> <li>• Insomnia</li> <li>• Dizziness, headache</li> <li>• Coughing, pharyngitis, sore throat</li> </ul> <p><b>Signs of overdosing or poisoning of Nicotine may occur in the following order:</b></p> <p>Nausea and/or vomiting; increased watering of mouth (severe); abdominal or stomach pain (severe); diarrhoea (severe); pale skin; cold sweat; headache (severe); dizziness (severe); disturbed hearing and vision; tremor; confusion; weakness (severe); extreme exhaustion; fainting; low blood pressure; difficulty in breathing (severe); fast, weak, or irregular heartbeat; convulsions (seizures).</p>

	Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as the body adjusts to the medicine.
<b>Management of complications</b>	<b>Smoking withdrawal symptoms</b> Ensure patient is using the recommended amount of NRT. Prompt medical officer to review care and consider combination therapy (e.g. patch to be used in combination with 2mg lozenge).
<b>Basis of Protocol/Guideline</b> (including sources of evidence, references)	<ul style="list-style-type: none"> <li>• Action on Smoking and Health (ASH).Guidance for health professionals on changes in the licensing arrangements for nicotine replacement therapy. London, December, 2005.</li> <li>• MIMS online.</li> <li>• Nicabate Product Information</li> <li>• NSW Health's Guide for the Management of Nicotine Dependent Inpatients.</li> <li>• Cappelleri J, Bushmakin A, Baker C, MerikleE, Oufade A, Gilbert D Revealing the multidimensional framework of the Minnesota nicotine withdrawal scale, Current medical research and opinion. 21(5): 749-60 May 2005</li> <li>• Medication Handling in NSW Public Hospitals PD2007_077</li> </ul>
<b>Groups consulted in development of this guideline</b>	Pharmacy, Clinical Governance, Nursing and Midwifery, John Hunter Hospital Obstetrics, NSW Health, Tamworth Base Obstetrics, Nursing & Midwifery Services