



## Nicotine Replacement Therapy During Pregnancy and Lactation

1. Non-pharmacological therapy (behavioural interventions and psychological support) is the treatment of choice for smoking cessation during pregnancy and lactation.<sup>1</sup>
2. Consider recommending Nicotine Replacement Therapy (NRT) if the patient is moderately or highly dependent on nicotine, smokes 20 or more cigarettes daily, or when psychological therapy has failed or is insufficient to control the cravings.<sup>1,2</sup>
  - The following two questions can be used to estimate the level of nicotine dependence:
    - (1) How much do you smoke on a typical day?
    - (2) How soon after you wake up do you smoke your first cigarette?<sup>3</sup>
  - Levels of dependence:
    - (1) *Highly nicotine dependent*: more than 20 cigarettes daily, first cigarette of the day within 30 minutes after waking.
    - (2) *Moderately dependent*: 16 – 19 cigarettes daily.
    - (3) *Low level of dependence*: 15 cigarettes or fewer daily.<sup>3</sup>
3. Discuss risks versus benefits of NRT with patient.<sup>1,2</sup> (Table 1)
4. Determine appropriate type and dose of NRT on a case-by-case basis and advise patient on appropriate use.<sup>1,2,4</sup> (Table 2)
  - **During pregnancy:** In general, as needed formulations of NRT are preferred – gum, lozenges, oral inhaler. If nausea & vomiting are concerns, the patch may be a better choice.<sup>1,4</sup>
  - **During lactation:** Mothers using as needed formulations of NRT (gum, lozenges, oral inhaler) should try to avoid breastfeeding for 2 – 3 hours after using these products as large variations in the concentration of nicotine in the mother's blood may occur during that period. If the patch is used, it should be removed at bedtime to reduce exposure of the baby to nicotine during night feedings.<sup>5,6</sup>
  - **During pregnancy and lactation:** Mothers should not continue to smoke while using NRT.<sup>3,5</sup>
5. Alternatives to NRT: first-line – bupropion; second-line - nortriptyline, clonidine (off-label indication - consider only if NRT and bupropion are contraindicated or not effective, and benefit outweighs risk).<sup>4</sup>

**TABLE 1: Benefits and Risks of NRT during Pregnancy and Lactation**

	<b>Benefits of NRT</b>	<b>Risks of NRT</b>
<b>Pregnancy</b>	Reduces withdrawal symptoms, eliminates exposure of mother and fetus to all the other harmful chemicals in cigarette smoke. <sup>1,2</sup>	A recent study in Denmark reported a slightly increased risk of congenital malformations in women using NRT versus women who continued to smoke during the first trimester of pregnancy. <sup>7</sup> The Motherisk Program still considers NRT to be safer than continued smoking. <sup>8</sup>
<b>Lactation</b>	Reduces withdrawal symptoms, eliminates exposure of mother and baby to all the other harmful chemicals in cigarette smoke, may help mother to quit smoking permanently <sup>1,2</sup>	A very small amount of nicotine is excreted in breast milk (milk to plasma ratio averages 2.9). <sup>5</sup> NRT products are believed to be safer for the baby than continued cigarette smoking but the risk potential is not fully known. <sup>6</sup>

**TABLE 2: Comparison of NRT Formulations <sup>4,5</sup>**

<b>NRT Type</b>	<b>Dose</b>	<b>Instructions</b>	<b>Benefits</b>	<b>Side Effects/ Disadvantages</b>
<b>Gum</b>	<ul style="list-style-type: none"> <li>◦ 2 mg or 4 mg / piece</li> <li>◦ 4 mg more effective for highly dependent smokers</li> <li>◦ Chew 1 piece for every 1-2 cig. up to 20 per day</li> <li>◦ Recommended duration of use is 3 months</li> </ul>	<ul style="list-style-type: none"> <li>◦ Chew slowly once or twice, then place between cheek and gums for about 1 min, then repeat for up to 30 min.</li> <li>◦ Do not eat or drink (other than water) while using</li> </ul>	<ul style="list-style-type: none"> <li>◦ Fast acting - peak conc. in 30 min.</li> <li>◦ Oral gratification</li> <li>◦ Flexible dosing to cope with cravings</li> </ul>	<ul style="list-style-type: none"> <li>◦ Mouth and throat irritation</li> <li>◦ GI upset</li> <li>◦ Jaw ache, headache</li> <li>◦ Adhesion to fillings, dentures</li> </ul>
<b>Inhaler</b>	<ul style="list-style-type: none"> <li>◦ Approx. 2 mg (4 puffs / min over 20 min)</li> <li>◦ 6 – 12 cartridges daily</li> <li>◦ Recommended duration of use is 3 months</li> </ul>	<ul style="list-style-type: none"> <li>◦ Attach cartridge to plastic mouthpiece and inhale at the same rate as when smoking.</li> </ul>	<ul style="list-style-type: none"> <li>◦ Fast acting - peak conc. in 15 min.</li> <li>◦ Oral gratification</li> <li>◦ Familiar hand-to-mouth ritual</li> <li>◦ Flexible dosing to cope with cravings</li> </ul>	<ul style="list-style-type: none"> <li>◦ Mouth and throat irritation</li> <li>◦ GI upset</li> <li>◦ Cough</li> <li>◦ Asthmatics should use with caution</li> </ul>
<b>Lozenge (NOC approved but n/a at time of printing)</b>	<ul style="list-style-type: none"> <li>◦ 2 mg or 4 mg / lozenge</li> <li>◦ 2 mg if time to 1<sup>st</sup> cig. is &gt; 30 minutes; 4 mg if &lt; 30 minutes</li> </ul>	<ul style="list-style-type: none"> <li>◦ Suck 1 lozenge slowly until it dissolves. Do not bite, chew or swallow.</li> <li>◦ Do not eat or drink for 15 min. before using.or while using.</li> </ul>	<ul style="list-style-type: none"> <li>◦ Fast acting - peak conc. in 30 min.</li> <li>◦ Oral gratification</li> <li>◦ Flexible dosing to cope with cravings</li> </ul>	<ul style="list-style-type: none"> <li>◦ Heartburn, nausea</li> <li>◦ Hiccups</li> </ul>
<b>Patch</b>	<ul style="list-style-type: none"> <li>◦ 7, 14 &amp; 21 mg</li> <li>◦ &gt; 20 cig/day: initiate with 21 mg/day for up to 6 weeks, then decrease dosage as directed..</li> <li>◦ &lt;20 cigs/day: initiate with 14 mg/day for up to 6 weeks, then decrease dosage as directed..</li> <li>◦ Recommended duration of use: 6 – 12 weeks</li> </ul>	<ul style="list-style-type: none"> <li>◦ Apply to new site each day and don't reuse same site for 7 days.</li> <li>◦ Apply first thing in the morning &amp; remove at bedtime.</li> </ul>	<ul style="list-style-type: none"> <li>◦ Continuous nicotine delivery.</li> <li>◦ Patient acceptance and ease of use.</li> </ul>	<ul style="list-style-type: none"> <li>◦ Redness, itching at patch site, headache, dizziness, fatigue, sleep disturbances and GI upset.</li> <li>◦ Contraindicated if severe skin disease, allergy to adhesive tape</li> <li>◦ Slow onset – levels increase gradually over 6 – 10 hrs; max. concentration in 2 – 3 days.</li> </ul>

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References available on the SDIS website, [www.usask.ca/druginfo](http://www.usask.ca/druginfo)

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