## NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS

<table>
<thead>
<tr>
<th>GUM</th>
<th>LOZENGE</th>
<th>TRANSDERMAL PATCH</th>
<th>NASAL SPRAY</th>
<th>ORAL INHALER</th>
<th>BUPROPION SR</th>
<th>VARENICLINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicorette¹, Generic</td>
<td>Nicorette¹, Generic Nicorette¹ Mini</td>
<td>NicoDerm CQ¹, Generic NicoDerm CQ (Nicoderm CQ, generic)</td>
<td>Nicotrol NS²</td>
<td>Nicotrol Inhaler²</td>
<td>Zyban¹, Generic</td>
<td>Chantix²</td>
</tr>
<tr>
<td>OTC 2 mg, 4 mg original, cinnamon, fruit, mint</td>
<td>OTC 2 mg, 4 mg; cherry, mint</td>
<td>7 mg, 14 mg, 21 mg (24-hr release)</td>
<td>Rx Metered spray 10 mg/mL nicotine solution</td>
<td>Rx 10 mg cartridge delivers 4 mg inhaled vapor</td>
<td>Rx 150 mg sustained-release tablet</td>
<td>0.5 mg, 1 mg tablet</td>
</tr>
</tbody>
</table>

### PRECAUTIONS

- Recent (≤ 2 weeks) myocardial infarction
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### DOSE

- **1st cigarette ≤30 minutes after waking:**
  - 4 mg
  - 2 mg
- **1st cigarette >30 minutes after waking:**
  - 4 mg
- Weeks 1–6:
  - 1 piece q 1–2 hours
  - 6–10 pieces/day
  - Maximum, 24 pieces/day
- Weeks 7–9:
  - 1 piece q 4–8 hours
  - Maximum, 20 lozenges/day
  - Allow to dissolve slowly (20–30 minutes for standard)
  - Nicotine release may cause a warm, tingling sensation
  - Do not chew or swallow
  - Occasionally rotate to different areas of mouth
  - No food or beverages 15 minutes before or during use
  - Duration: up to 12 weeks

- **1st cigarette ≤30 minutes after waking:**
  - 4 mg
  - 2 mg
- Weeks 1–6:
  - 1 lozenge q 1–2 hours
  - 7 mg/day x 2 weeks
  - ≤10 lozenges/day:
  - 14 mg/day x 6 weeks
  - 7 mg/day x 2 weeks
  - Rotate patch application site daily; do not apply a new patch to the same skin site for at least one week
  - May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime)
  - Duration: 6–10 weeks

- **1–2 doses/hour**
  - (8–40 doses/day)
  - One dose = 2 sprays (one in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa
  - Maximum: 2 doses/hour or ≤ 40 doses/day
  - For best results, initially use at least 8 doses/day
  - Do not sniff, swallow, or inhale through the nose as the spray is being administered
  - Duration: 3 months

- **6–16 cigarettes/day**
  - Individualize dosing; initially use 1 cigarette q 1–2 hours
  - Best effects with continuous puffing for 20 minutes
  - Initially use at least 6 cigarettes/day
  - Nicotine in cartridge is depleted after 20 minutes of active puffing
  - Inhale into back of throat or puff in short bursts
  - Do NOT inhale into the lungs (like a cigarette) but “puff” as if lighting a pipe
  - Open cartridge retains potency for 24 hours
  - No food or beverages 15 minutes before or during use
  - Duration: 3–6 months

- **150 mg po q AM x 3 days, then 150 mg po bid**
- **Do not exceed 300 mg/day**
- **Begin therapy 1–2 weeks prior to quit date**
- **Allow at least 8 hours between doses**
- **Avoid bedtime dosing to minimize insomnia**
- **Dose tapering is not necessary**
- **Duration: 7–12 weeks, with maintenance up to 6 months in selected patients**
- **Days 1–3:** 0.5 mg po AM daily
- **Days 4–7:** 0.5 mg po bid daily
- **Weeks 2–12:** 1 mg po bid daily
- **Begin therapy 1 week prior to quit date**
- **Take dose after eating and with a full glass of water**
- **Dose tapering is not necessary**
- **Dosing adjustment is necessary for patients with severe renal impairment**
- **Duration: 12 weeks; an additional 12-week course may be used in selected patients**
- **May initiate up to 35 days before target quit date OR may reduce smoking over a 12-week period of treatment prior to quitting and continue treatment for an additional 12 weeks**
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<tr>
<th>Gum</th>
<th>Lozenge</th>
<th>Transdermal Patch</th>
<th>Nasal Spray</th>
<th>Oral Inhaler</th>
<th>Bupropion SR</th>
<th>Varenicline</th>
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<tr>
<td><strong>ADVERSE EFFECTS</strong></td>
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<tr>
<td>Mouth and throat irritation</td>
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<td>Local skin reactions (erythema, pruritus, burning)</td>
<td>Nasal and/or throat irritation (hot, peppery, or burning sensation)</td>
<td>Mouth and/or throat irritation</td>
<td>Insomnia</td>
<td>Nausea</td>
</tr>
<tr>
<td>Jaw muscle soreness</td>
<td>Hiccups</td>
<td>Sleep disturbances (abnormal or vivid dreams, insomnia); associated with nocturnal nicotine absorption</td>
<td>Ocular irritation/tearing</td>
<td>Cough</td>
<td>Dry mouth</td>
<td>Sleep disturbances (insomnia, abnormal/vivid dreams)</td>
</tr>
<tr>
<td>Hiccups</td>
<td>Gl complaints (dyspepsia, nausea)</td>
<td>Sneezing</td>
<td>GI complaints (dyspepsia, nausea)</td>
<td>Hiccups</td>
<td>Nausea</td>
<td>Headache</td>
</tr>
<tr>
<td>May stick to dental work</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Anxiety/difficulty concentrating</td>
<td>Flatulence</td>
</tr>
<tr>
<td></td>
<td>Adverse effects more commonly experienced when chewing the lozenge or using incorrect gum chewing technique (due to rapid nicotine release):</td>
<td></td>
<td></td>
<td></td>
<td>Constipation</td>
<td>Taste alteration</td>
</tr>
<tr>
<td></td>
<td>Light headedness/dizziness</td>
<td></td>
<td></td>
<td></td>
<td>Rash</td>
<td>Neuropsychiatric symptoms (rare; see PRECAUTIONS)</td>
</tr>
<tr>
<td></td>
<td>Nausea/vomiting</td>
<td></td>
<td></td>
<td></td>
<td>Seizures (risk is 0.1%)</td>
<td>Constipation</td>
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<td></td>
<td>Hiccups</td>
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<td></td>
<td>Mouth and throat irritation</td>
<td></td>
<td></td>
<td></td>
<td>Patients should be monitored for potential neuropsychiatric symptoms</td>
<td>Cost of treatment</td>
</tr>
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<td></td>
<td></td>
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<td></td>
<td>(see PRECAUTIONS)</td>
<td>Cost of treatment</td>
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<td>Might serve as an oral substitute for tobacco</td>
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<td>Once-daily dosing associated with fewer adherence problems</td>
<td>Can be titrated to rapidly manage withdrawal symptoms</td>
<td>Might serve as an oral substitute for tobacco</td>
<td>Twice-daily oral dosing is simple and associated with fewer adherence problems</td>
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</tr>
<tr>
<td>Might delay weight gain</td>
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<td>Of all NRT products, its use is least obvious to others</td>
<td>Can be used in combination with other agents: delivers consistent nicotine levels over 24 hours</td>
<td>Can be titrated to manage withdrawal symptoms</td>
<td>Might delay weight gain</td>
<td>Offers a different mechanism of action for patients who have failed other agents</td>
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<tr>
<td>Can be titrated to manage withdrawal symptoms</td>
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<td>Can be used in combination with other agents: delivers consistent nicotine levels over 24 hours</td>
<td>Can be used in combination with other agents to manage situational urges</td>
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<td>Might be beneficial in patients with depression</td>
<td>Most effective cessation agent when used as monotherapy</td>
</tr>
<tr>
<td>Can be used in combination with other agents to manage situational urges</td>
<td>Can be used in combination with other agents to manage situational urges</td>
<td>Relatively inexpensive</td>
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<td>Can be used in combination with NRT agents</td>
<td>Most effective cessation agent when used as monotherapy</td>
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<tr>
<td>Relatively inexpensive</td>
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<td><strong>DISADVANTAGES</strong></td>
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<td>Need for frequent dosing can compromise adherence</td>
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<td>When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms</td>
<td>Need for frequent dosing can compromise adherence</td>
<td>Need for frequent dosing can compromise adherence</td>
<td>Seizure risk is increased</td>
<td>Patients should be monitored for potential neuropsychiatric symptoms</td>
</tr>
<tr>
<td>Might be problematic for patients with significant dental work</td>
<td>Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome</td>
<td>Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)</td>
<td>Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic</td>
<td>Cartridges might be less effective in cold environments (≤60°F)</td>
<td>Several contraindications and precautions preclude use in some patients (see PRECAUTIONS)</td>
<td>Patients should be monitored for potential neuropsychiatric symptoms</td>
</tr>
<tr>
<td>Proper chewing technique is necessary for effectiveness and to minimize adverse effects</td>
<td></td>
<td></td>
<td>Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease</td>
<td>Cost of treatment</td>
<td></td>
<td></td>
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<td>Gum chewing might not be acceptable or desirable for some patients</td>
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</tr>
</tbody>
</table>

### COST/DAY

<table>
<thead>
<tr>
<th></th>
<th>2 mg or 4 mg: $1.90–$3.60 (9 pieces)</th>
<th>2 mg or 4 mg: $3.33–$3.60 (9 pieces)</th>
<th>$1.52–$2.90 (1 patch)</th>
<th>$8.72 (8 doses)</th>
<th>$14.88 (6 cartridges)</th>
<th>$2.58–$8.25 (2 tablets)</th>
<th>$15.14 (2 tablets)</th>
</tr>
</thead>
</table>

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2 Marketed by GlaxoSmithKline.
3 Marketed by Pfizer.

The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

In July 2009, the FDA mandated that the prescribing information for all bupropion- and varenicline-containing products include a black-boxed warning highlighting the risk of serious neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide. Clinicians should advise patients to stop taking varenicline or bupropion SR and contact a health care provider immediately if they experience agitation, depressed mood, or any changes in behavior that are not typical of nicotine withdrawal, or if they experience suicidal thoughts or behavior. If treatment is stopped due to neuropsychiatric symptoms, patients should be monitored until the symptoms resolve. Based on results of a mandated clinical trial, the FDA removed this boxed warning in December 2016.

Approximate cost based on the recommended initial dosing for each agent and the wholesale acquisition cost from Red Book Online. Thomson Reuters, December 2018.

Abbreviations: MAO, monoamine oxidase; NRT, nicotine replacement therapy; OTC, over-the-counter (nonprescription product); Rx, prescription product.

For complete prescribing information and a comprehensive listing of warnings and precautions, please refer to the manufacturers' package inserts.

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