# NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS

<table>
<thead>
<tr>
<th>PRODUCT</th>
<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>Nicolette, ZONNIC, Generic OTC 2 mg, 4 mg original, cinnamon, fruit, mint</td>
<td>Nicolette Lozange,Generic OTC 2 mg, 4 mg; cherry, mint</td>
<td>NicoDerm CO, Generic OTC (NicoDerm CO, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hr release)</td>
<td>Nicotrol NS Rx Metered spray 10 mg/mL aqueous solution</td>
<td>Nicotrol Inhaler Rx 10 mg cartridge delivers 4 mg inhaled vapor</td>
<td>Chantix Rx 150 mg sustained-release tablet</td>
<td>Zyban, Generic 3 mg po AM x 3 days, then 150 mg po bid</td>
<td></td>
</tr>
</tbody>
</table>

Precautions:
- Recent (≤ 2 weeks) myocardial infarction
- Serious underlying arrhythmias
- Serious or worsening angina pectoris
- Pregnancy and breastfeeding
- Adolescents (<18 years)

Dosing:
- 1st cigarette ≤30 minutes after waking: 4 mg
- 1st cigarette >30 minutes after waking: 2 mg
- Weeks 1-6: 1 piece q 1-2 hours
- Weeks 7-9: 1 piece q 2-4 hours
- Weeks 10-12: 1 piece q 4-8 hours
- Maximum: 24 pieces/day
- Chew each piece slowly
- Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews)
- Resume chewing when tingle fades
- Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min)
- Park in 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
- 1st cigarette >30 minutes after waking: 2 mg
- Weeks 1-6: 1 lozenge q 1-2 hours
- Weeks 7-9: 1 lozenge q 2-4 hours
- Weeks 10-12: 1 lozenge q 4-8 hours
- Maximum: 20 lozenges/day
- Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini)
- Nicotine release may cause a warm, tingling sensation
- Do not chew or swallow
- Occasionally rotate to different areas of the mouth
- No food or beverages 15 minutes before or during use
- Duration: up to 12 weeks

- >10 cigarettes/day: 21 mg/day x 4–6 weeks
- 14 mg/day x 2 weeks
- 7 mg/day x 2 weeks
- ≤10 cigarettes/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: 8-10 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: 5–6 doses/hour or 40 doses/day
- For best results, initially use at least 8 doses per hour
- Do not sniff, swallow, or inhale through the nose as the spray is being administered
- Duration: 3–6 months

- 6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours
- Best effects with continuous puffing for 20 minutes
- Initially use at least 6 cartridges/day
- Nicotine in cartridge is depleted after 20 minutes of active puffing
- Inhalate into back of throat or puff in short breaths
- Do NOT inhalate 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 q AM
- Days 4–7: 0.5 mg po bid
- Weeks 2–12: 1 mg po bid
- 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
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><strong>ADVERSE EFFECTS</strong></td>
<td><strong>ADVANTAGES</strong></td>
<td><strong>DISADVANTAGES</strong></td>
<td><strong>COST/DAU</strong></td>
<td><strong>COST/DAU</strong></td>
<td><strong>COST/DAU</strong></td>
<td><strong>COST/DAU</strong></td>
</tr>
<tr>
<td>• Mouth/jaw soreness</td>
<td>• Might serve as an oral substitute for tobacco</td>
<td>• Need for frequent dosing can compromise adherence</td>
<td>2 mg or 4 mg: $1.90–$3.70 (9 pieces)</td>
<td>$2.58–$7.87 (2 tablets)</td>
<td>$10.50 (2 tablets)</td>
<td></td>
</tr>
<tr>
<td>• Hiccups</td>
<td>• Might delay weight gain</td>
<td>• Might be problematic for patients with significant dental work</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Dyspepsia</td>
<td>• Can be titrated to manage withdrawal symptoms</td>
<td>• Proper chewing technique is necessary for effectiveness and to minimize adverse effects</td>
<td>2 mg or 4 mg: $2.66–$4.10 (9 pieces)</td>
<td>$6.09 (8 doses)</td>
<td>$10.37 (6 cartridges)</td>
<td></td>
</tr>
<tr>
<td>• Hypersalivation</td>
<td>• Can be used in combination with other agents to manage situational urges</td>
<td>• Gum chewing might not be acceptable or desirable for some patients</td>
<td>$1.52–$3.48 (1 patch)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Effects associated with incorrect chewing technique: - Lightheadedness - Nausea/vomiting - Throut and mouth irritation</td>
<td></td>
<td>• Need for frequent dosing can compromise adherence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Can be used in combination with other agents to manage situational urges</td>
<td>• Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Need for frequent dosing can compromise adherence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Need for frequent dosing can compromise adherence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Cartridges might be less effective in cold environments (&lt;60°F)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Seizure risk is increased</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Several contraindications and precautions preclude use in some patients (see PRECAUTIONS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Patients should be monitored for potential neuropsychiatric symptoms5 (see PRECAUTIONS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Should be taken with food or a full glass of water to reduce the incidence of nausea</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Patients should be monitored for potential neuropsychiatric symptoms5 (see PRECAUTIONS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 Marketed by GlaxoSmithKline.
2 Marketed by Niconovum USA (a subsidiary of Reynolds American, Inc.)
3 Marketed by Pfizer.
4 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.
5 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.
6 Wholesale acquisition cost from Red Book Online. Thomson Reuters, January 2016.

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.

Copyright © 1999-2016 The Regents of the University of California. All rights reserved. Updated January 27, 2016.

Reprinted with permission.