# Pharmacologic Product Guide: FDA-Approved Medications for Smoking Cessation

## 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>Nicorette, Generic OTC</td>
<td>2 mg, 4 mg</td>
<td>original, cinnamon, fruit, mint (various)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Nicorette, Generic Nicorette Mini</td>
<td>2 mg, 4 mg</td>
<td>cinnamon, cherry, mint</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Habitrol, NicoDerm CO</td>
<td>7 mg, 14 mg, 21 mg (24-hr release)</td>
<td>1st cigarette &gt;30 minutes after original, cinnamon, fruit, mint (various)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nicotrol NS</td>
<td>Rx</td>
<td>Metered spray 10 mg/mL nicotine solution</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nicotrol Inhaler</td>
<td>Rx</td>
<td>10 mg cartridge delivers 4 mg inhaled vapor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generic (formerly Zyban)</td>
<td>Rx</td>
<td>150 mg sustained-release tablet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chantix</td>
<td>Rx</td>
<td>0.5 mg, 1 mg tablet</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

### PRECAUTIONS

- **Recent (< 2 weeks) myocardial infarction**
- Serious underlying arrhythmias
- Serious or worsening angina pectoris
- Temporomandibular joint disease
- Pregnancy and breastfeeding
- Adolescents (<18 years)

### DOSING

- **1st cigarette**: 
  - ≤30 minutes after waking: 4 mg
  - ≤30 minutes after waking: 2 mg
- **Weeks 1–6**: 
  - 1 mg po bid
  - 1 mg po q AM
- **Weeks 7–9**: 
  - 1 mg po q AM
- **Weeks 10–12**: 
  - 1 mg po q AM

- **Duration**: up to 12 weeks

<table>
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<tr>
<th>Week</th>
<th>Dose Frequency</th>
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<td>1–6</td>
<td>1 mg po bid</td>
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<td>1 mg po q AM</td>
</tr>
<tr>
<td>10–12</td>
<td>1 mg po q AM</td>
</tr>
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</table>

### CONTRAINDICATIONS

- Seizure disorder
- Concomitant bupropion (e.g., Wellbutrin) therapy
- Current or prior diagnosis of bulimia or anorexia nervosa
- Simultaneous abrupt discontinuation of alcohol or sedatives/benzodiazepines
- MAO inhibitors in preceding 14 days; concurrent use of reversible MAO inhibitors

### ADVERSE REACTIONS

- Severe renal impairment (dosage adjustment is necessary)
- Pregnancy and breastfeeding
- Adolescents (<18 years)
- Treatment-emergent neuropsychiatric symptoms

### Notes

- Dose tapering is not necessary
- May initiate up to 35 days prior to quitting date
- 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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**Nicorette**: Delivers 0.5 mg of nicotine to the nasal mucosa.

**Nicorette Mini**: Delivers 2 mg of nicotine to the oral cavity.

**Habitrol**: Delivers 2 mg of nicotine to the buccal mucosa.

**Nicotrol**: Delivers 10 mg/mL nicotine solution inhaled vapor.

**Nicotrol Inhaler**: Delivers 4 mg of nicotine inhaled vapor.

**Bupropion SR**: 150 mg sustained-release tablet.

**Varenicline**: 0.5 mg, 1 mg tablet.

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**Nicotine Replacement Therapy (NRT)** formulations are available in various strengths and formulations to help individuals quit smoking. Each option is designed to help in different stages of quitting, and their use is often monitored by healthcare providers to ensure safety and efficacy.
## NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS

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<tbody>
<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>• Nausea</td>
</tr>
<tr>
<td>• Hiccups</td>
<td>• GI complaints (dyspepsia, nausea)</td>
<td>• Sneezing</td>
<td>• Cough</td>
<td>• Hiccups</td>
<td>• Anxiety/difficulty concentrating</td>
<td>• Constipation</td>
</tr>
<tr>
<td>• GI complaints (dyspepsia, nausea)</td>
<td>• May stick to dental work</td>
<td>• GI complaints (dyspepsia, nausea)</td>
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<td>• GI complaints (dyspepsia, nausea)</td>
<td>• Rash</td>
<td>• Tolerance</td>
</tr>
<tr>
<td>• Adverse effects more commonly experienced when chewing the lozenge or using incorrect gum chewing technique (due to rapid nicotine release):</td>
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<td>• Seizures (risk is 0.15%)</td>
<td>• Neuropsychiatric symptoms (rare; see PRECAUTIONS)</td>
</tr>
</tbody>
</table>
  - Lightheadedness/dizziness |  |  |  |  |  |  |
  - Nausea/vomiting |  |  |  |  |  |  |
  - Hiccups |  |  |  |  |  |  |
  - Mouth and throat irritation |  |  |  |  |  |  |

### ADVERSE EFFECTS

1. Might serve as an oral substitute for tobacco
2. Might delay weight gain
3. Can be titrated to manage withdrawal symptoms
4. Can be used in combination with other agents to manage situational urges
5. Relatively inexpensive

### ADVANTAGES

1. Need for frequent dosing can compromise adherence
2. Might be problematic for patients with significant dental work
3. Proper chewing technique is necessary for effectiveness and to minimize adverse effects
4. Gum chewing might not be acceptable or desirable for some patients

### DISADVANTAGES

1. Need for frequent dosing can compromise adherence
2. Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome
3. When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms
4. Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)
5. Need for frequent dosing can compromise adherence
6. Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic
7. Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease
8. Need for frequent dosing can compromise adherence
9. Cartridges might be less effective in cold environments (≤60°F)
10. Cost of treatment

### COST/DAY

| 2 mg or 4 mg: $1.90–$5.49 (9 pieces) | 2 mg or 4 mg: $2.97–$4.23 (9 pieces) | $1.52–$3.49 (1 patch) | $9.64 (6 doses) | $16.38 (6 cartridges) | $0.72 (2 tablets) | $17.20 (2 tablets) |

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1. Marketed by GlaxoSmithKline.
2. Marketed by Dr. Reddy’s.
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. Based on results of a mandated clinical trial, the FDA removed this boxed warning in December 2016.
6. Approximate cost based on the recommended initial dosing for each agent and the wholesale acquisition cost from Red Book Online. Thomson Reuters, January 2021.

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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