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

## Nicotine Replacement Therapy (NRT) Formulations

<table>
<thead>
<tr>
<th>Product</th>
<th>Gum</th>
<th>Lozenges</th>
<th>Transdermal Patch</th>
<th>Nasal Spray</th>
<th>Oral Inhaler</th>
<th>Bupropion SR</th>
<th>Varenicline</th>
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<tbody>
<tr>
<td>Nicorette®, Generic OTC</td>
<td>2 mg, 4 mg original, cinnamon, fruit, mint (various)</td>
<td>Nicorette®, Generic Nicorette® 1 Mini OTC</td>
<td>2 mg, 4 mg; cinnamon, cherry, mint</td>
<td>Nicotrol NS1 Rx 150 mg sustained-release tablet</td>
<td>Nicotrol Inhaler2 Rx 10 mg cartridge delivers 4 mg inhaled vapor</td>
<td>Generic (formerly Zyban) Rx 150 mg sustained-release tablet</td>
<td>Chantix®, Generic Rx 0.5 mg, 1 mg tablet</td>
</tr>
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### Precautions
- Recent (≤ 2 weeks) myocardial infarction
- Serious underlying arrhythmias
- Serious or worsening angina pectoris
- Temporomandibular joint disease
- Pregnancy and breastfeeding
- Adolescents (<18 years)
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- Recent (≤ 2 weeks) myocardial infarction
- Serious underlying arrhythmias
- Serious or worsening angina pectoris
- Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis)
- Severe reactive airway disease
- Pregnancy and breastfeeding
- Adolescents (<18 years)
- Concomitant therapy with medications/conditions known to lower the seizure threshold
- Hepatic impairment
- Pregnancy and breastfeeding
- Adolescents (<18 years)
- Treatment-emergent neuropsychiatric symptoms

### 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

### 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*

- **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*

- **≥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); before recommending, rule out other factors that might be contributing (e.g., drug interaction between caffeine and tobacco smoke, other medications, and lifestyle factors)
- Duration: 6–10 weeks

- 1–2 doses/hour*
- (6–40 doses/day)
- One dose = 2 sprays (one in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa
- *while awake

- Maximum – 5 doses/hour or 40 doses/day
- During initial 6 weeks of treatment, use at least 6 cartridges/day
- Gradually reduce daily dosage over the following 6–12 weeks
- Nicotine in cartridge is depleted after 20 minutes of active puffing
- Don’t sniff, swallow, or inhale through the nose as the spray is being administered
- Duration: 12 weeks

- 6–16 cartridges/day
- Individualize dosing; initially use 1 cartridge q 1–2 hours*
- *while awake

- Best effects with continuous puffing for 20 minutes
- During initial 6 weeks of treatment use at least 6 cartridges/day
- Gradually reduce daily dosage over the following 4–6 weeks
- Inhalo into back of throat or puff in short breaths
- 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
- 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
- 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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<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, p orry, 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>- Headache</td>
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<td>- Hiccups</td>
<td>- GI complaints (dyspepsia, nausea)</td>
<td>- Sneezing</td>
<td>- Cough</td>
<td>- Hiccups</td>
<td>- Anxiety/difficulty concentrating</td>
<td>- Flatulence</td>
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<td>- May stick to dental work</td>
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<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>- Lightheadedness/dizziness</td>
<td>- Nausea</td>
<td>- Insomnia (abnormal or vivid dreams, insomnia); associated with nocturnal nicotine absorption</td>
<td>- Cough</td>
<td>- Nausea</td>
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<td>- Seizures (risk is 0.15%)</td>
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<td>- Nausea/vomiting</td>
<td>- Dry mouth</td>
<td>- Sleep disturbances (abnormal or vivid dreams, insomnia); associated with nocturnal nicotine absorption</td>
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<td>- Neuropsychiatric symptoms (rare; see PRECAUTIONS)</td>
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<td>- Hiccups</td>
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<td>- When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms</td>
<td>- Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic</td>
<td>- Seizure risk is increased</td>
<td>- Several contraindications and precautions preclude use in some patients (see PRECAUTIONS)</td>
<td>- Patients should be monitored for potential neuropsychiatric symptoms(^1) (see PRECAUTIONS)</td>
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<td>- Proper chewing technique is necessary for effectiveness and to minimize adverse effects</td>
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### Advantages

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

### Disadvantages

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

### Cost

| 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 (8 doses) | $16.38 (6 cartridges) | $0.72 (2 tablets) | $17.20 (Chantix) (2 tablets) |

\(^1\) 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, September 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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