## 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, ZONNIC, Generic OTC</td>
<td>2 mg, 4 mg original, cinnamon, fruit, mint</td>
<td>Nicorette Lozenges, Nicorette Mini Lozenges, Generic OTC 2 mg, 4 mg; cherry, mint</td>
<td>Nicoderm CQ, Generic OTC (NicoDerm CQ, 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>Zyban, Generic Rx 150 mg sustained-release tablet</td>
<td>Chantix Rx 0.5 mg, 1 mg tablet</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
- **1st cigarette >30 minutes after waking:** 2 mg

**Weeks 1-6:**
- 1 piece q 1-2 hours
- 1 piece q 2-4 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

- **10 cigarettes/day:** 1 mg po bid
- **1 cigarette ≤30 minutes after waking:** 4 mg
- **1 cigarette >30 minutes after waking:** 2 mg
- **Weeks 1-6:**
  - 1 lozenge q 1-2 hours
  - 1 lozenge q 2-4 hours
  - 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

- **1-2 doses/hour:**
  - **10 cigarettes/day:** 14 mg/day x 2 weeks
  - **≤10 cigarettes/day:** 7 mg/day x 2 weeks
  - **Maximum:** 5 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:** 3–6 months

- **1-2 cigarettes/day:** 21 mg/day x 4-6 weeks
  - **One dose = 2 sprays (one in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa**
  - **Maximum:** 5 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:** 8-10 weeks

- **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**
  - **Inhale 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

- **Duration:** 3–6 months

- **Duration:** 12 weeks

**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

**Bupropion SR:**
- **Dose tapering is not necessary**
  - **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**

**Varenicline:**
- **Concomitant therapy with medications/conditions known to lower the seizure threshold**
- **Hepatic impairment**
- **Pregnancy** (category C) and breastfeeding
- **Adolescents (<18 years)**
- **Treatment-emergent neuropsychiatric symptoms**: **BOXED WARNING REMOVED 12/2016**
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<tr>
<td>- Mouth/jaw soreness</td>
<td>- Nausea</td>
<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>- Hiccups</td>
<td>- Headache</td>
<td>- Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption</td>
<td>- Cough</td>
<td>- Cough</td>
<td>- Dry mouth</td>
<td>- Sleep disturbances (insomnia, abnormal/vivid dreams)</td>
</tr>
<tr>
<td>- Dyspepsia</td>
<td>- Heartburn</td>
<td>- Flatulence</td>
<td>- Headache</td>
<td>- Headache</td>
<td>- Nervousness/difficulty concentrating</td>
<td>- Constipation</td>
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<td>- Hypersalivation</td>
<td>- Headache</td>
<td>- Insomnia</td>
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<td>- Dizziness</td>
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<td>- Effects associated with incorrect chewing technique.</td>
<td>- Lightheadedness</td>
<td>- Effects associated with incorrect administration</td>
<td>- Effects associated with incorrect administration</td>
<td>- Effects associated with incorrect administration</td>
<td>- Rash</td>
<td>- Vomiting</td>
</tr>
<tr>
<td>- Nausea/vomiting</td>
<td>- Rash</td>
<td>- Increased salivation (with higher nicotine levels over 24 hours)</td>
<td>- Headache</td>
<td>- Headache</td>
<td>- Seizures (risk is 0.1%)</td>
<td>- Neuropsychiatric symptoms (rare; see PRECAUTIONS)</td>
</tr>
<tr>
<td>- Throat and mouth irritation</td>
<td>- Headache</td>
<td>- Effects associated with incorrect administration</td>
<td>- Diaphoresis</td>
<td>- Diaphoresis</td>
<td>- Urinary retention</td>
<td>- Nausea</td>
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</tbody>
</table>

### 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
- 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

### 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/Day

- **Gum:** 2 mg or 4 mg: $1.90–$3.70 (9 pieces)
- **Lozenge:** 2 mg or 4 mg: $3.36–$3.78 (9 pieces)
- **Transdermal Patch:** $1.52–$3.48 (1 patch)
- **Nasal Spray:** $6.67 (8 doses)
- **Oral Inhaler:** $11.35 (6 cartridges)
- **Bupropion SR:** $2.58–$7.87 (2 tablets)
- **Varenicline:** $11.86 (2 tablets)

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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. Based on results of a mandated clinical trial, the FDA removed this boxed warning in December 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.

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