# 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>Varenclline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicorette, ZONNIC, Generic</td>
<td>Nicorette Lozenge,</td>
<td>Nicorette Mini Lozenge,</td>
<td>Nicoderm CQ, Generic</td>
<td>Nicotrol Inhaler,</td>
<td>Zyban, Generic</td>
<td>Nicorette SR</td>
<td>Chantix</td>
</tr>
<tr>
<td>OTC 2 mg, 4 mg</td>
<td>OTC 2 mg, 4 mg</td>
<td>Rx (generic)</td>
<td>Rx (generic)</td>
<td>Rx</td>
<td>Rx</td>
<td>0.5 mg, 1 mg tablet</td>
<td></td>
</tr>
<tr>
<td>original, cinnamon, fruit, mint</td>
<td>cherry, mint</td>
<td>7 mg, 14 mg, 21 mg (24-hr release)</td>
<td>Metered spray</td>
<td>10 mg/mL aqueous solution</td>
<td>Rx 10 mg cartridge delivers 4 mg inhaled vapor</td>
<td>0.5 mg, 1 mg tablet</td>
<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:**
  - 1–2 doses/hour
  - One dose = 2 sprays (one in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa
  - Best effects with continuous puffing for 20 minutes
  - Inhalation: 8–10 cartridges/day

- **1st cigarette >30 minutes after waking:**
  - 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 (ingle 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:**
  - Individualize dosing; initially use 1 cartridge q 1–2 hours
  - Inhalation: 8–10 cartridges/day

- **6–16 cartridges/day:**
  - Individualize dosing; initially use 1 cartridge q 1–2 hours
  - Inhalation: 8–10 cartridges/day

### 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

### OTC (Nicorette Mini Lozenge, Generic)

- 2 mg, 4 mg; cherry, mint

### NicoDerm CQ (Rx (generic) 7 mg, 14 mg, 21 mg (24-hr release)

- 0.5 mg, 1 mg tablet

### Chantix

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

### BOXED WARNING REMOVED

- 12/2016

### BOXED WARNING REMOVED

- 12/2016

### 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
### NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS

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<tr>
<td>Mouth/jaw soreness</td>
<td>Mouth irritation</td>
<td>Local skin reactions (erythema, pruritus, burning)</td>
<td>Nasal and/or throat irritation (hot, peppery, or burning sensation)</td>
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<tr>
<td>Nausea</td>
<td>Nausea</td>
<td>Headache</td>
<td>Headache</td>
<td>Cough</td>
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</tr>
<tr>
<td>Headache</td>
<td>Heartburn</td>
<td>Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption</td>
<td>Rhinoitis</td>
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<tr>
<td>Headache</td>
<td>Sore throat</td>
<td></td>
<td>Tearing</td>
<td>Dizziness</td>
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### ADVERSE EFFECTS

- Mouth/jaw soreness
- Nausea
- Headache
- Heartburn
- Local skin reactions (erythema, pruritus, burning)
- Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption
- Dizziness

- Mouth irritation
- Nausea
- Headache
- Sore throat
- Dizziness

- Dry mouth
- Nervousness/difficulty concentrating
- Nausea
- Dizziness
- Constipation
- Rash
- Seizures (risk is 0.1%)
- Neuropsychiatric symptoms (rare; see PRECAUTIONS)

### 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

### 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

### COSTS/DAY

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<tr>
<td>2 mg or 4 mg: $1.90–$3.60 (9 pieces)</td>
<td>2 mg or 4 mg: $3.33–$3.60 (9 pieces)</td>
<td>$1.52–$2.90 (1 patch)</td>
<td>$7.30 (8 doses)</td>
<td>$12.42 (6 cartridges)</td>
<td>$2.58–$8.25 (2 tablets)</td>
<td>$11.88 (2 tablets)</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. 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, June 2017.

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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