### 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>
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</thead>
<tbody>
<tr>
<td>Nicorette®, Generic OTC</td>
<td>2 mg, 4 mg</td>
<td>2 mg, 4 mg</td>
<td>NicoDerm CQ®, Generic OTC (Nicopatch) 7 mg, 14 mg, 21 mg</td>
<td>Nicotrol NS® Metered spray 10 mg/mL nicotine solution</td>
<td>Nicotrol Inhaler® 10 mg cartridge delivers 4 mg inhaled vapor</td>
<td>Zyban®, Generic 150 mg sustained-release tablet</td>
<td>Chantix® 0.5 mg, 1 mg tablet</td>
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</table>

#### Precautions

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

#### Dosing

**Nicorette®**
- **Gum**
  - **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

**Nicorette® Mini OTC**
- **Lozenge**
  - **1st cigarette ≤30 minutes after waking:** 2 mg
  - **1st cigarette >30 minutes after waking:** 4 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)
  - **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

**NicoDerm CQ®, Generic OTC**
- **Transdermal Patch**
  - **1st cigarette ≤30 minutes after waking:** 2 mg
  - **1st cigarette >30 minutes after waking:** 4 mg
  - **Weeks 1–6:** 7 mg/day x 2 weeks
  - **Weeks 7–9:** 7 mg/day x 2 weeks
  - **Weeks 10–12:** 7 mg/day x 2 weeks
  - **Maximum:** - 5 doses/hour or - 40 doses/day
  - **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:** 3–6 months

**Nicotrol NS®**
- **Nasal Spray**
  - **Metered spray 10 mg/mL nicotine solution**
  - **1–2 doses/hour (4–80 doses/day)**
  - **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:** 6–16 weeks

**Nicotrol Inhaler®**
- **Oral Inhaler**
  - **10 mg cartridge delivers 4 mg inhaled vapor**
  - **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**
  - **Duration:** 12 weeks
  - **Simultaneous abrupt discontinuation of alcohol or sedatives/benzodiazepines**
  - **MAO inhibitors in preceding 14 days; concurrent use of reversible MAO inhibitors**

**Chantix®**
- **Rx**
  - **0.5 mg, 1 mg tablet**
  - **Duration:** 12 weeks

**Zyban®, Generic**
- **Dosage Adjustment:**
  - **Concomitant therapy with medications/conditions known to lower the seizure threshold**
  - **Hepatic impairment**
  - **Treatment-emergent neuropsychiatric symptoms**
  - **Boxed warning removed 12/2016**

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

**Bupropion SR**
- **Rx**
  - **150 mg sustained-release tablet**
  - **Duration:** 12 weeks
  - **Simultaneous abrupt discontinuation of alcohol or sedatives/benzodiazepines**
  - **MAO inhibitors in preceding 14 days; concurrent use of reversible MAO inhibitors**

**Chantix®**
- **Dosage 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**
  - **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
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<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>
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<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>• Sleep disturbances (insomnia, abnormal/vivid dreams)</td>
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<td>• Hiccups</td>
<td>• GI complaints (dyspepsia, nausea)</td>
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<td>• Sneezing</td>
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<td>• Headache</td>
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<td>• GI complaints (dyspepsia, nausea)</td>
<td>• May stick to dental work</td>
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<td>• Cough</td>
<td>• GI complaints (dyspepsia, nausea)</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>• Constipation</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>
<td>• - Lightheadedness/dizziness</td>
<td>• Once-daily dosing associated with fewer adherence problems</td>
<td>• Can be titrated to rapidly manage withdrawal symptoms</td>
<td>• Might serve as an oral substitute for tobacco</td>
<td>• Nausea</td>
<td>• Taste alteration</td>
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<td></td>
<td>• - Nausea/vomiting</td>
<td>• Of all NRT products, its use is least obvious to others</td>
<td>• Can be used in combination with other agents to manage situational urges</td>
<td>• Can be titrated to manage withdrawal symptoms</td>
<td>• Sleep disturbances (insomnia); associated with nocturnal nicotine absorption</td>
<td>• Neuropsychiatric symptoms (rare; see Precautions)</td>
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<td>• - Hiccups</td>
<td>• Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours</td>
<td>• Can be used in combination with other agents to manage situational urges</td>
<td>• Might serve as an oral substitute for tobacco</td>
<td>• Seizures (risk is 0.1%)</td>
<td>• Neuropsychiatric symptoms (rare; see Precautions)</td>
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<td>• - Mouth and throat irritation</td>
<td>• Relatively inexpensive</td>
<td>• Can be used in combination with other agents to manage situational urges</td>
<td>• Can be used in combination with NRT agents</td>
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<td>• Might serve as an oral substitute for tobacco</td>
<td>• Might delay weight gain</td>
<td>• Can be titrated to manage withdrawal symptoms</td>
<td>• Can be used in combination with other agents to manage situational urges</td>
<td>• Can be used in combination with NRT agents</td>
<td>• Most effective cessation agent when used as monotherapy</td>
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<td>• Need for frequent dosing can compromise adherence</td>
<td>• Might be problematic for patients with significant dental work</td>
<td>• Proper chewing technique is necessary for effectiveness and to minimize adverse effects</td>
<td>• Gum chewing might not be acceptable or desirable for some patients</td>
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<td>• Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome</td>
<td>• When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms</td>
<td>• Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)</td>
<td>• Need for frequent dosing can compromise adherence</td>
<td>• Several contraindications and precautions preclude use in some patients (see Precautions)</td>
<td>• Neuropsychiatric symptoms (rare; see Precautions)</td>
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<td>2 mg or 4 mg: $1.90–$5.49</td>
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<td>$1.52–$3.49</td>
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<td>$14.98</td>
<td>$2.58–$8.25</td>
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1. Marketed by GlaxoSmithKline.
2. Marketed by Pfizer.
3. 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.
4. 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.
5. Approximate cost based on the recommended initial dosage for each agent and the wholesale acquisition cost from Red Book Online. Thomson Reuters, January 2019.

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.