## 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>Varencliene</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicorette 1, ZONNIC 2, Generic</td>
<td>Nicorette Lozenges, 1 Nicorette Mini Lozenges, 1</td>
<td>Nicoderm CQ, Generic Rx (generic) 7 mg, 14 mg, 21 mg (24-hr release)</td>
<td>Metered spray 10 mg/mL aqueous solution</td>
<td>Nicotrol NS Rx (generic) 7 mg/mL aqueous solution</td>
<td>Nicotrol Inhaler Rx (generic) 10 mg cartridge delivers 4 mg inhaled vapor</td>
<td>Zyban Rx 150 mg sustained-release tablet</td>
<td>Chantix Rx 0.5 mg, 1 mg tablet</td>
</tr>
<tr>
<td></td>
<td>OTC 2 mg, 4 mg original, cinnamon, fruit, mint</td>
<td>NicoDerm CQ, Generic Rx (generic) 7 mg/mL aqueous solution</td>
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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)

#### DOSING

<table>
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<tr>
<th>1st cigarette ≤ 30 minutes after waking:</th>
<th>1st cigarette &gt; 30 minutes after waking:</th>
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<tr>
<td>1 mg</td>
<td>2 mg</td>
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</table>

#### STORAGE

- Store at room temperature (15–30°C).
- Protect from light and moisture.

#### ADVERSE EFFECTS

- Nausea
- Headache
- Dizziness
- Dry mouth

#### CONTRAINDICATIONS

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

#### WARNING

- BLACK-BOXED WARNING for 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 (e.g., linezolid, methylene blue)

#### DOSING

- 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 1–2 weeks prior to quit date
- Allow at least 8 hours between doses
- Avoid bedtime dosing to minimize insomnia
- Dose tapering is not necessary
- Duration: 7–12 weeks, with maintenance up to 6 months in selected patients

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<td><strong>Mouth/jaw soreness</strong></td>
<td><strong>Nausea</strong></td>
<td><strong>Local skin reactions (erythema, pruritus, burning)</strong></td>
<td><strong>Nasal and/or throat irritation (hot, peppery, or burning sensation)</strong></td>
<td><strong>Mouth and/or throat irritation</strong></td>
<td><strong>Insomnia</strong></td>
<td><strong>Nausea</strong></td>
</tr>
<tr>
<td><strong>Hiccups</strong></td>
<td><strong>Heartburn</strong></td>
<td><strong>Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption</strong></td>
<td><strong>Cough</strong></td>
<td><strong>Cough</strong></td>
<td><strong>Dry mouth</strong></td>
<td><strong>Sleep disturbances (insomnia, abnormal/vivid dreams)</strong></td>
</tr>
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<td><strong>Dyspepsia</strong></td>
<td><strong>Headache</strong></td>
<td><strong>Rhinitis</strong></td>
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<td><strong>Nervousness/difficulty concentrating</strong></td>
<td><strong>Constipation</strong></td>
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<td><strong>Hypersalivation</strong></td>
<td><strong>Flatulence</strong></td>
<td><strong>Tearing</strong></td>
<td><strong>Dizziness</strong></td>
<td><strong>Constipation</strong></td>
<td><strong>Sensitivity to light</strong></td>
<td><strong>Flatulence</strong></td>
</tr>
<tr>
<td><strong>Effects associated with incorrect chewing technique:</strong></td>
<td><strong>Insomnia</strong></td>
<td><strong>Cough</strong></td>
<td><strong>Nasal and/or oral bleeding</strong></td>
<td><strong>Vomiting</strong></td>
<td><strong>Seizures (risk is 0.1%)</strong></td>
<td><strong>Nasopulmonary symptoms (rare; see PRECAUTIONS)</strong></td>
</tr>
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<td>– Lightheadedness</td>
<td>– Nausea/vomiting</td>
<td></td>
<td>– Flatulence</td>
<td>– Vomiting</td>
<td>– Neurological symptoms</td>
<td>– Psychiatric symptoms</td>
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<td>– Throat and mouth irritation</td>
<td></td>
<td>– Dizziness</td>
<td></td>
<td>– Rash</td>
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<td>– Psychiatric symptoms</td>
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### ADVERSE EFFECTS

- **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**
- **Might serve as an oral substitute for tobacco**
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### ADVANTAGES

- **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**
- **Need for frequent dosing can compromise adherence**
- **Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome**
- **When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms**
- **Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)**
- **Need for frequent dosing can compromise adherence**
- **Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic**
- **Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease**
- **Seizure risk is increased**
- **Several contraindications and precautions preclude use in some patients (see PRECAUTIONS)**
- **Patients should be monitored for potential neurocognitive symptoms**

### DISADVANTAGES

- **2 mg or 4 mg: $1.90–$3.70 (9 pieces)**
- **2 mg or 4 mg: $2.66–$4.10 (9 pieces)**
- **$1.52–$3.48 (1 patch)**
- **$6.09 (6 doses)**
- **$10.37 (6 cartridges)**
- **$2.58–$7.87 (2 tablets)**
- **$10.50 (2 tablets)**

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.
6 Wholesale acquisition cost from Red Book Online. Thomson Reuters, January 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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