

# Pharmacologic Product Guide

## FDA-Approved Medications for Smoking Cessation

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS						Bupropion SR	Varenicline
	Gum	Lozenge	Transdermal Patch	Nasal Spray	Oral Inhaler		
PRODUCT	<p><b>Nicorette<sup>1</sup>, ZONNIC<sup>2</sup>, Generic</b> OTC 2 mg, 4 mg original, cinnamon, fruit, mint,</p>	<p><b>Nicorette Lozenge<sup>1</sup>, Nicorette Mini Lozenge<sup>1</sup>, Generic</b> OTC 2 mg, 4 mg cherry, mint</p>	<p><b>NicoDerm CQ<sup>1</sup>, Generic</b> OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)</p>	<p><b>Nicotrol NS<sup>3</sup></b> Rx Metered spray 10 mg/mL aqueous nicotine solution</p>	<p><b>Nicotrol Inhaler<sup>3</sup></b> Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor</p>	<p><b>Zyban<sup>1</sup>, Generic</b> Rx 150 mg sustained-release tablet</p>	<p><b>Chantix</b> Rx 0.5 mg, 1 mg tablet</p>
PRECAUTIONS	<ul style="list-style-type: none"> <li>Recent (≤2 weeks) myocardial infarction</li> <li>Serious underlying arrhythmias</li> <li>Serious or worsening angina pectoris</li> <li>Temporomandibular joint disease</li> <li>Pregnancy<sup>3</sup> and breastfeeding</li> <li>Adolescents (&lt;18 years)</li> </ul>	<ul style="list-style-type: none"> <li>Recent (≤2 weeks) myocardial infarction</li> <li>Serious underlying arrhythmias</li> <li>Serious or worsening angina pectoris</li> <li>Pregnancy<sup>3</sup> and breastfeeding</li> <li>Adolescents (&lt;18 years)</li> </ul>	<ul style="list-style-type: none"> <li>Recent (≤2 weeks) myocardial infarction</li> <li>Serious underlying arrhythmias</li> <li>Serious or worsening angina pectoris</li> <li>Pregnancy<sup>3</sup> (Rx formulations, category D) and breastfeeding</li> <li>Adolescents (&lt;18 years)</li> </ul>	<ul style="list-style-type: none"> <li>Recent (≤2 weeks) myocardial infarction</li> <li>Serious underlying arrhythmias</li> <li>Serious or worsening angina pectoris</li> <li>Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis)</li> <li>Severe reactive airway disease</li> <li>Pregnancy<sup>3</sup> (category D) and breastfeeding</li> <li>Adolescents (&lt;18 years)</li> </ul>	<ul style="list-style-type: none"> <li>Recent (&lt;2 weeks) myocardial infarction</li> <li>Serious underlying arrhythmias</li> <li>Serious or worsening angina pectoris</li> <li>Bronchospastic disease</li> <li>Pregnancy<sup>3</sup> (category D) and breastfeeding</li> <li>Adolescents (&lt;18 years)</li> </ul>	<ul style="list-style-type: none"> <li>Concomitant therapy with medications or medical conditions known to lower the seizure threshold</li> <li>Hepatic impairment</li> <li>Pregnancy<sup>3</sup> (category C) and breastfeeding</li> <li>Adolescents (&lt;18 years)</li> <li>Treatment-emergent neuropsychiatric symptoms<sup>5</sup>: Boxed warning removed 12/2016</li> </ul> <p><b>Contraindications:</b></p> <ul style="list-style-type: none"> <li>Seizure disorder</li> <li>Concomitant bupropion (e.g., Wellbutrin) therapy</li> <li>Current or prior diagnosis of bulimia or anorexia nervosa</li> <li>Simultaneous abrupt discontinuation of alcohol or sedatives (including benzodiazepines)</li> <li>MAO inhibitor therapy in previous 14 days; concurrent use of reversible MAO inhibitors (e.g., linezolid, methylene blue)</li> </ul>	<ul style="list-style-type: none"> <li>Severe renal impairment (dosage adjustment is necessary)</li> <li>Pregnancy<sup>3</sup> (category C) and breastfeeding</li> <li>Adolescents (&lt;18 years)</li> <li>Treatment-emergent neuropsychiatric symptoms<sup>5</sup>: Boxed warning removed 12/2016</li> </ul>
DOSING	<p>1st cigarette ≤30 minutes after waking: 4mg 1st cigarette &gt;30 minutes after waking: 2 mg</p> <p>Week 1–6: 1 piece q 1–2 hours Week 7–9: 1 piece q 2–4 hours Week 10–12: 1 piece q 4–8 hours</p> <ul style="list-style-type: none"> <li>Maximum, 24 pieces/day</li> <li>Chew each piece slowly</li> <li>Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews)</li> <li>Resume chewing when tingle fades</li> <li>Repeat chew/park steps until most of the nicotine is gone (taste or tingle does not return; generally 30 min)</li> <li>Park in different areas of mouth</li> <li>No food or beverages 15 min before or during use</li> <li>Duration: up to 12 weeks</li> </ul>	<p>1st cigarette ≤30 minutes after waking: 4 mg 1st cigarette &gt;30 minutes after waking: 2 mg</p> <p>Week 1–6: 1 lozenge q 1–2 hours Week 7–9: 1 lozenge q 2–4 hours Week 10–12: 1 lozenge q 4–8 hours</p> <ul style="list-style-type: none"> <li>Maximum: 20 lozenges/day</li> <li>Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini lozenge)</li> <li>Nicotine release may cause a warm, tingling sensation</li> <li>Do not chew or swallow</li> <li>Occasionally rotate to different areas of the mouth</li> <li>No food or beverages 15 min before or during use</li> <li>Duration: up to 12 weeks</li> </ul>	<p>&gt;10 cigarettes/day: 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks</p> <p>≤10 cigarettes/day: 14 mg/day x 6 weeks 7 mg/day x 2 weeks</p> <ul style="list-style-type: none"> <li>Rotate patch application site daily; do not apply a new patch to the same skin site for at least one week</li> <li>May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime)</li> <li>Duration: 8–10 weeks</li> </ul>	<p>1–2 doses/hour (8–40 doses/day) One dose = 2 sprays (one in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa</p> <ul style="list-style-type: none"> <li>Maximum: - 5 doses/hour or - 40 doses/day</li> <li>For best results, initially use at least 8 doses/day</li> <li>Patients should not sniff, swallow, or inhale through the nose as the spray is being administered</li> <li>Duration: 3–6 months</li> </ul>	<p>6–16 cartridges/day Individualized dosing; initially use 1 cartridge q 1–2 hours</p> <ul style="list-style-type: none"> <li>Best effects with continuous puffing for 20 minutes</li> <li>Initially use at least 6 cartridges/day</li> <li>Nicotine in cartridge is depleted after 20 minutes of active puffing</li> <li>Inhale into back of throat or puff in short breaths</li> <li>Do NOT inhale into the lungs (like a cigarette) but “puff” as if lighting a pipe</li> <li>Open cartridge retains potency for 24 hours</li> <li>No food or beverages 15 minutes before or during use</li> <li>Duration: 3–6 months</li> </ul>	<p>150 mg po q AM x 3 days, then increase to 150 mg po bid</p> <ul style="list-style-type: none"> <li>Do not exceed 300 mg/day</li> <li>Begin therapy 1–2 weeks <u>prior</u> to quit date</li> <li>Allow at least 8 hours between doses</li> <li>Avoid bedtime dosing to minimize insomnia</li> <li>Dose tapering is not necessary</li> <li>Duration: 7–12 weeks, with maintenance up to 6 months in selected patients</li> </ul>	<p>Days 1–3: 0.5 mg po q AM Days 4–7: 0.5 mg po bid Weeks 2–12: 1 mg po bid</p> <ul style="list-style-type: none"> <li>Begin therapy 1 week <u>prior</u> to quit date</li> <li>Take dose after eating with a full glass of water</li> <li>Dose tapering is not necessary</li> <li>Dosing adjustment is necessary for patients with severe renal impairment</li> <li>Duration: 12 weeks; an additional 12 week course may be used in selected patients</li> <li>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</li> </ul>

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<b>ADVERSE EFFECTS</b>	<ul style="list-style-type: none"> <li>Mouth/jaw soreness</li> <li>Hiccups</li> <li>Dyspepsia</li> <li>Hypersalivation</li> <li>Effects associated with incorrect chewing technique:               <ul style="list-style-type: none"> <li>Lightheadedness</li> <li>Nausea/vomiting</li> <li>Throat and mouth irritation</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Mouth irritation</li> <li>Nausea</li> <li>Hiccups</li> <li>Cough</li> <li>Heartburn</li> <li>Headache</li> <li>Dizziness</li> </ul>	<ul style="list-style-type: none"> <li>Local skin reactions (erythema, pruritus, burning)</li> <li>Headache</li> <li>Sleep disturbances (insomnia or abnormal/vivid dreams); associated with nocturnal nicotine absorption</li> </ul>	<ul style="list-style-type: none"> <li>Nasal and/or throat irritation (hot, peppery, or burning sensation)</li> <li>Rhinitis</li> <li>Tearing</li> <li>Sneezing</li> <li>Cough</li> <li>Headache</li> </ul>	<ul style="list-style-type: none"> <li>Mouth and/or throat irritation</li> <li>Cough</li> <li>Headache</li> <li>Rhinitis</li> <li>Dyspepsia</li> <li>Hiccups</li> </ul>	<ul style="list-style-type: none"> <li>Insomnia</li> <li>Dry mouth</li> <li>Nervousness/difficulty concentrating</li> <li>Nausea</li> <li>Dizziness</li> <li>Rash</li> <li>Constipation</li> <li>Seizures (risk is 0.1%)</li> <li>Neuropsychiatric symptoms (rare; see PRECAUTIONS)</li> </ul>	<ul style="list-style-type: none"> <li>Nausea</li> <li>Sleep disturbances (insomnia, abnormal/vivid dreams)</li> <li>Constipation</li> <li>Flatulence</li> <li>Vomiting</li> <li>Neuropsychiatric symptoms (rare: see PRECAUTIONS)</li> </ul>
<b>ADVANTAGES</b>	<ul style="list-style-type: none"> <li>Might serve as an oral substitute for tobacco</li> <li>Might delay weight gain</li> <li>Can be titrated to manage withdrawal symptoms</li> <li>Variety of flavors are available</li> <li>Can be used in combination with other agents to manage situational urges</li> </ul>	<ul style="list-style-type: none"> <li>Might serve as an oral substitute for tobacco</li> <li>Might delay weight gain</li> <li>Can be titrated to manage withdrawal symptoms</li> <li>Can be used in combination with other agents to manage situational urges</li> </ul>	<ul style="list-style-type: none"> <li>Once-daily dosing associated with fewer compliance problems</li> <li>Of all NRT products, its use is least obvious to others</li> <li>Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours</li> </ul>	<ul style="list-style-type: none"> <li>Can be titrated to rapidly manage withdrawal symptoms</li> <li>Can be used in combination with other agents to manage situational urges</li> </ul>	<ul style="list-style-type: none"> <li>Might serve as an oral substitute for tobacco</li> <li>Can be titrated to manage withdrawal symptoms</li> <li>Mimics hand-to-mouth ritual of smoking (could also be perceived as a disadvantage)</li> <li>Might satisfy oral cravings</li> <li>Can be used in combination with other NRT products to manage situational urges</li> </ul>	<ul style="list-style-type: none"> <li>Twice-daily oral dosing is simple and associated with fewer adherence problems</li> <li>Might delay weight gain</li> <li>Can be used in combination with NRT agents</li> </ul>	<ul style="list-style-type: none"> <li>Twice-daily oral dosing is simple and associated with fewer adherence problems</li> <li>Offers a different mechanism of action for patients who have failed other agents</li> </ul>
<b>DISADVANTAGES</b>	<ul style="list-style-type: none"> <li>Need for frequent dosing can compromise adherence</li> <li>Might be problematic for patients with significant dental work</li> <li>Proper chewing technique is necessary for effectiveness and to minimize adverse effects</li> <li>Need for frequent dosing can compromise compliance</li> <li>Gum chewing may not be socially acceptable or desirable for some patients</li> </ul>	<ul style="list-style-type: none"> <li>Need for frequent dosing can compromise compliance</li> <li>Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome</li> </ul>	<ul style="list-style-type: none"> <li>When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms</li> <li>Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)</li> </ul>	<ul style="list-style-type: none"> <li>Need for frequent dosing can compromise compliance</li> <li>Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic</li> <li>Not recommended for patients with chronic nasal disorders or severe reactive airway disease</li> </ul>	<ul style="list-style-type: none"> <li>Need for frequent dosing can compromise adherence</li> <li>Cost of treatment</li> <li>Cartridges should not be stored in very warm conditions (<math>\leq 60^{\circ}\text{F}</math>) or used in very cold conditions</li> </ul>	<ul style="list-style-type: none"> <li>Seizure risk is increased</li> <li>Several contraindications and precautions preclude use in some patients (see PRECAUTIONS)</li> <li>Patients should be monitored for potential neuropsychiatric symptoms<sup>5</sup> (see PRECAUTIONS)</li> </ul>	<ul style="list-style-type: none"> <li>Should be taken with food or a full glass of water to reduce incidence of nausea</li> <li>Patients should be monitored for potential neuropsychiatric symptoms<sup>5</sup> (see PRECAUTIONS)</li> </ul>
<b>COST/DAY<sup>4</sup></b>	2 mg or 4 mg: \$1.90 – \$3.60 (9 pieces)	2 mg or 4 mg: \$3.33 – \$3.60 (9 pieces)	\$1.52 – \$2. (1 patch)	\$7.30 (8 doses)	\$12.42 (6 cartridges)	\$2.58 – \$8.25 (2 tablets)	\$11.88 (2 tablets)

<sup>1</sup> Marketed by GlaxoSmithKline.

<sup>2</sup> Marketed by Pfizer.

<sup>3</sup> The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and hypothetical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

<sup>4</sup> Wholesale acquisition cost from Red Book Online. Thomson Reuters, March 2014.

Abbreviations: MAO, monoamine oxidase; NRT, nicotine replacement therapy; OTC, (over-the-counter) non-prescription product; Rx = prescription product.

**For complete prescribing information, please refer to the manufacturers' package inserts.**

