

# PHARMACOLOGIC PRODUCT GUIDE: FDA-APPROVED MEDICATIONS

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS								BUPROPION SR	VARENICLINE
GUM		LOZENGE	TRANSDERMAL PREPARATIONS <sup>1</sup>		NASAL SPRAY	ORAL INHALER			
PRODUCT	<b>Nicorette<sup>2</sup>, Generic</b> OTC 2 mg, 4 mg original, fruit, mint, orange, cinnamon	<b>Commit<sup>2</sup>, Generic</b> OTC 2 mg, 4 mg mint, cherry	<b>Nicoderm CQ<sup>2</sup></b> OTC 24-hour release 7 mg, 14 mg, 21 mg	<b>Generic Patch</b> OTC/Rx (formerly Habitrol) 24-hour release 7 mg, 14 mg, 21 mg	<b>Nicotrol NS<sup>3</sup></b> Rx Metered spray 0.5 mg nicotine in 50 µL aqueous nicotine solution	<b>Nicotrol Inhaler<sup>3</sup></b> Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	<b>Zyban<sup>2</sup>, Generic</b> Rx 150 mg sustained-release tablet	<b>Chantix<sup>3</sup></b> Rx 0.5 mg, 1 mg tablet	
PRECAUTIONS	<ul style="list-style-type: none"> <li>■ Pregnancy category: Not applicable for OTC formulations</li> <li>■ Recent (≤ 2 weeks) myocardial infarction</li> <li>■ Serious underlying arrhythmias</li> <li>■ Serious or worsening angina pectoris</li> <li>■ Temporomandibular joint disease</li> </ul>	<ul style="list-style-type: none"> <li>■ Pregnancy category: Not applicable for OTC formulations</li> <li>■ Recent (≤ 2 weeks) myocardial infarction</li> <li>■ Serious underlying arrhythmias</li> <li>■ Serious or worsening angina pectoris</li> </ul>	<ul style="list-style-type: none"> <li>■ Pregnancy category: D for prescription patch, not applicable for OTC formulations</li> <li>■ Recent (≤ 2 weeks) myocardial infarction</li> <li>■ Serious underlying arrhythmias</li> <li>■ Serious or worsening angina pectoris</li> </ul>	<ul style="list-style-type: none"> <li>■ Pregnancy category: D</li> <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> </ul>	<ul style="list-style-type: none"> <li>■ Pregnancy category: D</li> <li>■ Recent (≤ 2 weeks) myocardial infarction</li> <li>■ Serious underlying arrhythmias</li> <li>■ Serious or worsening angina pectoris</li> <li>■ Bronchospastic disease</li> </ul>	<ul style="list-style-type: none"> <li>■ Pregnancy category: C</li> <li>■ Concomitant therapy with medications or medical conditions known to lower the seizure threshold</li> <li>■ Severe hepatic cirrhosis</li> <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</li> </ul>	<ul style="list-style-type: none"> <li>■ Pregnancy category: C</li> <li>■ Severe renal impairment (dosage adjustment is necessary)</li> </ul> <p><b>Warnings:</b></p> <ul style="list-style-type: none"> <li>■ Neuropsychiatric symptoms</li> <li>■ Safety and efficacy have not been established in patients with serious psychiatric illness</li> </ul>		
DOSING	<p>≥25 cigarettes/day: 4 mg &lt;25 cigarettes/day: 2 mg</p> <p>Week 1 – 6: 1 piece q 1 – 2 hours</p> <p>Week 7 – 9: 1 piece q 2 – 4 hours</p> <p>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 taste or 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</p> <p>Week 7 – 9: 1 lozenge q 2 – 4 hours</p> <p>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)</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 minutes before or during use</li> <li>■ Duration: up to 12 weeks</li> </ul>	<p>&gt;10 cigarettes/day: 21 mg/day x 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>■ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime)</li> <li>■ Duration: 8 – 10 weeks</li> </ul>	<p>&gt;10 cigarettes/day: 21 mg/day x 4 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>■ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime)</li> <li>■ Duration: 8 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 - 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>■ Nicotine in cartridge is depleted after 20 minutes of active puffing</li> <li>■ Patient should 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>■ Duration: up to 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>■ Treatment should be initiated while patient is still smoking</li> <li>■ Set quit date 1 – 2 weeks after initiation of therapy</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>■ Can be used safely with NRT</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</p> <p>Days 4 – 7: 0.5 mg po bid</p> <p>Weeks 2 – 12: 1 mg po bid</p> <ul style="list-style-type: none"> <li>■ Patients should begin therapy 1 week prior to quit date</li> <li>■ Take dose after eating with a full glass of water</li> <li>■ Dose tapering is not necessary</li> <li>■ Nausea and insomnia are side effects that are usually temporary</li> <li>■ Duration: 12 weeks; an additional 12 week course may be used in selected patients</li> </ul>	

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ADVERSE EFFECTS	GUM	LOZENGE	TRANSDERMAL PREPARATIONS		NASAL SPRAY	ORAL INHALER		
			NICODERM CQ	GENERIC PATCH				
ADVERSE EFFECTS	<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>■ Nausea</li> <li>■ Hiccups</li> <li>■ Cough</li> <li>■ Heartburn</li> <li>■ Headache</li> <li>■ Flatulence</li> <li>■ Insomnia</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>■ Unpleasant taste</li> <li>■ Cough</li> <li>■ Rhinitis</li> <li>■ Dyspepsia</li> <li>■ Hiccups</li> <li>■ Headache</li> </ul>	<ul style="list-style-type: none"> <li>■ Insomnia</li> <li>■ Dry mouth</li> <li>■ Nervousness/difficulty concentrating</li> <li>■ Rash</li> <li>■ Constipation</li> <li>■ Seizures (risk is 1/1,000 [0.1%])</li> </ul>	<ul style="list-style-type: none"> <li>■ Nausea</li> <li>■ Sleep disturbances (insomnia, abnormal dreams)</li> <li>■ Constipation</li> <li>■ Flatulence</li> <li>■ Vomiting</li> </ul>
ADVANTAGES	<ul style="list-style-type: none"> <li>■ Gum use might satisfy oral cravings</li> <li>■ Gum use may delay weight gain</li> <li>■ Patients can titrate therapy to manage withdrawal symptoms</li> </ul>	<ul style="list-style-type: none"> <li>■ Lozenge use might satisfy oral cravings</li> <li>■ Lozengese might delay weight gain</li> <li>■ Patients can titrate therapy to manage withdrawal symptom</li> </ul>	<ul style="list-style-type: none"> <li>■ Provides consistent nicotine levels over 24 hours</li> <li>■ Easy to use and conceal</li> <li>■ Once-a-day dosing associated with fewer compliance problems</li> </ul>		<ul style="list-style-type: none"> <li>■ Patients can titrate therapy to manage withdrawal symptoms</li> </ul>	<ul style="list-style-type: none"> <li>■ Patients can titrate therapy to manage withdrawal symptoms</li> <li>■ Mimics hand-to-mouth ritual of smoking</li> </ul>	<ul style="list-style-type: none"> <li>■ Easy to use; oral formulation might be associated with fewer compliance problems</li> <li>■ Can be used with NRT</li> <li>■ Might be beneficial in patients with depression</li> </ul>	<ul style="list-style-type: none"> <li>■ Easy to use; oral formulation might be associated with fewer compliance problems</li> <li>■ Offers a new mechanism of action for patients who have failed other agents</li> </ul>
DISADVANTAGES	<ul style="list-style-type: none"> <li>■ Gum chewing may not be socially acceptable</li> <li>■ Gum is difficult to use with dentures</li> <li>■ Patients must use proper chewing technique to minimize adverse effects</li> </ul>	<ul style="list-style-type: none"> <li>■ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome</li> </ul>	<ul style="list-style-type: none"> <li>■ Patients cannot titrate the dose</li> <li>■ Allergic reactions to adhesive might occur</li> <li>■ Patients with dermatologic conditions should not use the patch</li> </ul>		<ul style="list-style-type: none"> <li>■ Nasal/throat irritation may be bothersome</li> <li>■ Dependence can result</li> <li>■ Patients must wait 5 minutes before driving or operating heavy machinery</li> <li>■ Patients with chronic nasal disorders or severe reactive airway disease should not use the spray</li> </ul>	<ul style="list-style-type: none"> <li>■ Initial throat or mouth irritation can be bothersome</li> <li>■ Cartridges should not be stored in very warm conditions or used in very cold conditions</li> <li>■ Patients with underlying bronchospastic disease must use the inhaler with caution</li> </ul>	<ul style="list-style-type: none"> <li>■ Seizure risk is increased</li> <li>■ Several contraindications and precautions preclude use (see PRECAUTIONS)</li> </ul>	<ul style="list-style-type: none"> <li>■ May induce nausea in up to one third of patients</li> <li>■ Post-marketing surveillance data not yet available</li> </ul>
WEBSITE	www.nicorette.com	www.commitlozenge.com	www.nicodermcq.com	www.habitrol.com	www.nicotrol.com	www.nicotrol.com	----	www.chantix.com
COST/DAY <sup>4</sup>	2 mg: \$3.28 – \$6.57 (9 pieces) 4 mg: \$4.31 – \$6.51 (9 pieces)	2 mg: \$3.66 – \$5.26 (9 pieces) 4 mg: \$3.66 – \$5.26 (9 pieces)	\$2.24 – \$3.89 (1 patch)	\$1.90 – \$2.94 (1 patch)	\$3.67 (8 doses)	\$5.29 (6 cartridges)	\$3.62 – \$6.04 (2 tablets)	\$4.00 – \$4.22 (2 tablets)

04/08

<sup>1</sup> Transdermal patch formulations previously marketed, but no longer available: Nicotrol 5 mg, 10 mg, 15 mg delivered over 16 hours (Pfizer) and generic patch (formerly Prostep) 11 mg and 22 mg delivered over 24 hours.

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

<sup>3</sup> Marketed by Pfizer.

<sup>4</sup> Average wholesale price from 2007 Drug Topics Redbook. Montvale, NJ: Medical Economics Company, Inc., June 2007.

Abbreviations: Hx = history; 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.**

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