



# 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	Nicorette <sup>2</sup> , Generic OTC 2 mg, 4 mg; original, FreshMint <sup>2</sup> , Fruit Chill <sup>2</sup> , mint, orange <sup>2</sup>	Commit <sup>2</sup> , Generic OTC 2 mg, 4 mg mint	Nicoderm CQ <sup>2</sup> OTC 24-hour release 7 mg, 14 mg, 21 mg	Generic Patch OTC/Rx (formerly Habitrol) 24-hour release 7 mg, 14 mg, 21 mg	Nicotrol NS <sup>3</sup> Rx Metered spray 0.5 mg nicotine in 50 µL aqueous nicotine solution	Nicotrol Inhaler <sup>3</sup> Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	Zyban <sup>2</sup> , Generic Rx 150 mg sustained-release tablet	Chantix <sup>3</sup> Rx 0.5 mg, 1 mg tablet
PRECAUTIONS	<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>▪ Temporomandibular joint 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> </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> </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> </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</li> </ul>	<ul style="list-style-type: none"> <li>▪ Pregnancy (Category C)</li> <li>▪ Severe renal impairment (dosage adjustment is necessary)</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>1<sup>st</sup> cigarette ≤30 minutes after waking: 4 mg 1<sup>st</sup> 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 <ul style="list-style-type: none"> <li>– 5 doses/hour</li> <li>– 40 doses/day</li> </ul> </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</p> <ul style="list-style-type: none"> <li>▪ Initially, use at least 6 cartridges/day</li> <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>

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS								BUPROPION SR	VARENICLINE
GUM	LOZENGE	TRANSDERMAL PREPARATIONS		NASAL SPRAY	ORAL INHALER				
		NICODERM CQ	GENERIC PATCH						
<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>▪ 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>		
<b>ADVANTAGES</b>	<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>▪ Patients can titrate therapy to manage withdrawal symptoms</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>		
<b>DISADVANTAGES</b>	<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, above)</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>		
<b>WEB-SITE</b>	www.nicorette.com	www.commitlozenge.com	www.nicodermcq.com	www.habitrol.com	www.nicotrol.com	www.nicotrol.com	----	www.chantix.com	
<b>COST/DAY<sup>4</sup></b>	2 mg: \$2.65–\$5.16 (9 pieces) 4 mg: \$3.18–\$5.81 (9 pieces)	2 mg: \$4.92 (9 pieces) 4 mg: \$5.26 (9 pieces)	\$3.35–\$3.91 (1 patch)	\$2.10–\$2.94 (1 patch)	\$3.67 (8 doses)	\$5.25–\$6.07 (6 cartridges)	\$3.62–\$5.73 (2 tablets)	\$4.00–\$4.22 (2 tablets)	

<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 2006 Drug Topics Redbook. Montvale, NJ: Medical Economics Company, Inc., December 2006.

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.**

Copyright © 1999-2007 The Regents of the University of California, University of Southern California, and Western University of Health Sciences. All rights reserved.