



PHARMACOLOGIC PRODUCT GUIDE: FDA-APPROVED MEDICATIONS

		NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS				BUPROPION SR	VARENICLINE
		GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY		
PRODUCT	Nicorette ¹ , Generic OTC 2 mg, 4 mg; original, cinnamon, fruit, mint (various), orange	Commit ¹ , Generic OTC 2 mg, 4 mg cappuccino, cherry, original (light-mint), mint	NicoDerm CQ ¹ , Generic ² OTC (Nicoderm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)	Nicotrol NS ³ Rx Metered spray 0.5 mg nicotine in 50 mL aqueous nicotine solution	Nicotrol Inhaler ³ Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	Zyban ¹ , Generic Rx 150 mg sustained-release tablet	Chantix ³ Rx 0.5 mg, 1 mg tablet
PRECAUTIONS	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Temporomandibular joint disease Pregnancy category: not applicable for OTC formulations 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy category: not applicable for OTC formulations 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy category: D for prescription patch, not applicable for OTC formulations 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) Severe reactive airway disease Pregnancy category: D 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Bronchospastic disease Pregnancy category: D 	<ul style="list-style-type: none"> Concomitant therapy with medications or medical conditions known to lower the seizure threshold Severe hepatic cirrhosis Patients with depressive or psychiatric disorders Pregnancy category: C <p>Contraindications:</p> <ul style="list-style-type: none"> Seizure disorder Concomitant bupropion (e.g., Wellbutrin) therapy Current or prior diagnosis of bulimia or anorexia nervosa Simultaneous abrupt discontinuation of alcohol or sedatives (including benzodiazepines) MAO inhibitor therapy in previous 14 days 	<ul style="list-style-type: none"> Severe renal impairment (dosage adjustment is necessary) <p>Warnings:</p> <ul style="list-style-type: none"> Neuropsychiatric symptoms (behavior changes, agitation, depressed mood, suicidal ideation or behavior) Safety and efficacy have not been established in patients with serious psychiatric illness Pregnancy category: C
DOSING	<p>≥25 cigarettes/day: 4 mg <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"> 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 taste or tingle fades Repeat chew/park steps until most of the nicotine is gone (taste or tingle does not return; generally 30 min) Park in different areas of mouth No food or beverages 15 min before or during use Duration: up to 12 weeks 	<p>1st cigarette ≤30 minutes after waking: 4 mg 1st cigarette >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"> 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 	<p>>10 cigarettes/day: 21 mg/day x 4 weeks (generic) 6 weeks (Nicoderm CQ)</p> <p>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"> May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) Duration: 8–10 weeks 	<p>1–2 doses/hour (8–40 doses/day)</p> <p>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"> Maximum <ul style="list-style-type: none"> – 5 doses/hour – 40 doses/day For best results, initially use at least 8 doses/day Patients should not sniff, swallow, or inhale through the nose as the spray is being administered Duration: 3–6 months 	<p>6–16 cartridges/day</p> <p>Individualize dosing; initially use 1 cartridge q 1–2 hours</p> <ul style="list-style-type: none"> Best effects with continuous puffing for 20 minutes Initially use at least 6 cartridges/day Nicotine in cartridge is depleted after 20 minutes of active puffing Patient should inhale into back of throat or puff in short breaths Do NOT inhale into the lungs (like a cigarette) but “puff” as if lighting a pipe Open cartridge retains potency for 24 hours Duration: 3–6 months 	<p>150 mg po q AM x 3 days, then increase to 150 mg po bid</p> <ul style="list-style-type: none"> Do not exceed 300 mg/day Treatment should be initiated while patient is still smoking Set quit date 1–2 weeks after initiation of therapy Allow at least 8 hours between doses Avoid bedtime dosing to minimize insomnia Dose tapering is not necessary Can be used safely with NRT Duration: 7–12 weeks, with maintenance up to 6 months in selected patients 	<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"> Patients should begin therapy 1 week prior to quit date Take dose after eating with a full glass of water Dose tapering is not necessary Nausea and insomnia are side effects that are usually temporary Duration: 12 weeks; an additional 12 week course may be used in selected patients

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS							BUPROPION SR	VARENICLINE
GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER				
ADVERSE EFFECTS	<ul style="list-style-type: none"> ▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: <ul style="list-style-type: none"> – Lightheadedness – Nausea/vomiting – Throat and mouth irritation 	<ul style="list-style-type: none"> ▪ Nausea ▪ Hiccups ▪ Cough ▪ Heartburn ▪ Headache ▪ Flatulence ▪ Insomnia 	<ul style="list-style-type: none"> ▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption 	<ul style="list-style-type: none"> ▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache 	<ul style="list-style-type: none"> ▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups 	<ul style="list-style-type: none"> ▪ Insomnia ▪ Dry mouth ▪ Nervousness/difficulty concentrating ▪ Rash ▪ Constipation ▪ Seizures (risk is 1/1,000 [0.1%]) 	<ul style="list-style-type: none"> ▪ Nausea ▪ Sleep disturbances (insomnia, abnormal/vivid dreams) ▪ Constipation ▪ Flatulence ▪ Vomiting ▪ Neuropsychiatric symptoms (rare; see PRECAUTIONS, above) 	
ADVANTAGES	<ul style="list-style-type: none"> ▪ Might satisfy oral cravings ▪ Might delay weight gain ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Variety of flavors are available 	<ul style="list-style-type: none"> ▪ Might satisfy oral cravings ▪ Might delay weight gain ▪ Easy to use and conceal ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Variety of flavors are available 	<ul style="list-style-type: none"> ▪ Provides consistent nicotine levels over 24 hours ▪ Easy to use and conceal ▪ Once daily dosing associated with fewer compliance problems 	<ul style="list-style-type: none"> ▪ Patients can titrate therapy to rapidly manage withdrawal symptoms 	<ul style="list-style-type: none"> ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking (could also be perceived as a disadvantage) 	<ul style="list-style-type: none"> ▪ Easy to use; oral formulation might be associated with fewer compliance problems ▪ Can be used with NRT ▪ Might be beneficial in patients with depression 	<ul style="list-style-type: none"> ▪ Easy to use; oral formulation might be associated with fewer compliance problems ▪ Offers a new mechanism of action for patients who have failed other agents 	
DISADVANTAGES	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Might be problematic for patients with significant dental work ▪ Patients must use proper chewing technique to minimize adverse effects ▪ Gum chewing may not be socially acceptable 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome 	<ul style="list-style-type: none"> ▪ Patients cannot titrate the dose to acutely manage withdrawal symptoms ▪ Allergic reactions to adhesive might occur ▪ Patients with dermatologic conditions should not use the patch 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Nasal/throat irritation may be bothersome ▪ Patients must wait 5 minutes before driving or operating heavy machinery ▪ Patients with chronic nasal disorders or severe reactive airway disease should not use the spray 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Initial throat or mouth irritation can be bothersome ▪ Cartridges should not be stored in very warm conditions or used in very cold conditions ▪ Patients with underlying bronchospastic disease must use the inhaler with caution 	<ul style="list-style-type: none"> ▪ Seizure risk is increased ▪ Several contraindications and precautions preclude use in some patients (see PRECAUTIONS, above) 	<ul style="list-style-type: none"> ▪ May induce nausea in up to one third of patients ▪ Post-marketing surveillance data indicate potential for neuropsychiatric symptoms (see PRECAUTIONS, above) 	
WEB-SITE	www.nicorette.com	www.commitlozenge.com	www.nicodermcq.com www.habitrol.com	www.nicotrol.com	www.nicotrol.com	---	www.chantix.com	
COST/DAY⁴	2 mg: \$3.28–\$6.58 (9 pieces) 4 mg: \$4.31–\$6.58 (9 pieces)	2 mg: \$3.66–\$5.26 (9 pieces) 4 mg: \$3.66–\$5.26 (9 pieces)	\$1.90–\$3.89 (1 patch)	\$3.72 (8 doses)	\$5.29 (6 cartridges)	\$3.62–\$7.40 (2 tablets)	\$4.49–\$4.75 (2 tablets)	

¹ Marketed by GlaxoSmithKline.

² Transdermal patch formulation previously marketed as Habitrol.

³ Marketed by Pfizer.

⁴ Average wholesale price from Medi-Span Electronic Drug File. Indianapolis, IN: Wolters Kluwer Health, September 2008.

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 © 1999–2009 The Regents of the University of California, University of Southern California, and Western University of Health Sciences. All rights reserved.

Updated September 18, 2008.