



PHARMACOLOGIC PRODUCT GUIDE: FDA-APPROVED MEDICATIONS

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS						BUPROPION SR	VARENICLINE	
GUM		LOZENGE	TRANSDERMAL PREPARATIONS ¹		NASAL SPRAY			ORAL INHALER
PRODUCT	Nicorette ² , Generic OTC 2 mg, 4 mg; original, FreshMint ² , Fruit Chill ² mint, orange ²	Commit ² , Generic OTC 2 mg, 4 mg mint	Nicoderm CQ ² 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 ³ Rx Metered spray 0.5 mg nicotine in 50 µL aqueous nicotine solution	Nicotrol Inhaler ³ Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	Zyban ² , Generic Rx 150 mg sustained-release tablet	Chantix ³ Rx 0.5 mg, 1 mg tablet
PRECAUTIONS	<ul style="list-style-type: none"> ▪ Pregnancy (Category D) ▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Temporomandibular joint disease 	<ul style="list-style-type: none"> ▪ Pregnancy (Category D) ▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris 	<ul style="list-style-type: none"> ▪ Pregnancy (Category D) ▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris 	<ul style="list-style-type: none"> ▪ Pregnancy (Category D) ▪ 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 	<ul style="list-style-type: none"> ▪ Pregnancy (Category D) ▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Bronchospastic disease 	<ul style="list-style-type: none"> ▪ Pregnancy (Category C) ▪ Concomitant therapy with medications or medical conditions known to lower the seizure threshold ▪ Severe hepatic cirrhosis <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"> ▪ Pregnancy (Category C) ▪ Severe renal impairment (dosage adjustment is necessary) 	
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 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"> ▪ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) ▪ Duration: 8–10 weeks 	<p>>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"> ▪ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) ▪ Duration: 8 weeks 	<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"> ▪ 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; individualized dosing</p> <ul style="list-style-type: none"> ▪ Initially, use at least 6 cartridges/day ▪ Best effects with continuous puffing for 20 minutes ▪ 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: up to 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								
	GUM	LOZENGE	TRANSDERMAL PREPARATIONS		NASAL SPRAY	ORAL INHALER	BUPROPION SR	VARENICLINE
			NICODERM CQ	GENERIC PATCH				
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) or 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 ▪ Unpleasant taste ▪ Cough ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups ▪ Headache 	<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 dreams) ▪ Constipation ▪ Flatulence ▪ Vomiting
ADVANTAGES	<ul style="list-style-type: none"> ▪ Gum use might satisfy oral cravings ▪ Gum use may delay weight gain ▪ Patients can titrate therapy to manage withdrawal symptoms 	<ul style="list-style-type: none"> ▪ Lozenge use might satisfy oral cravings ▪ Patients can titrate therapy to manage withdrawal symptoms 	<ul style="list-style-type: none"> ▪ Provides consistent nicotine levels over 24 hours ▪ Easy to use and conceal ▪ Once-a-day dosing associated with fewer compliance problems 		<ul style="list-style-type: none"> ▪ Patients can titrate therapy to manage withdrawal symptoms 	<ul style="list-style-type: none"> ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking 	<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"> ▪ Gum chewing may not be socially acceptable ▪ Gum is difficult to use with dentures ▪ Patients must use proper chewing technique to minimize adverse effects 	<ul style="list-style-type: none"> ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome 	<ul style="list-style-type: none"> ▪ Patients cannot titrate the dose ▪ Allergic reactions to adhesive might occur ▪ Patients with dermatologic conditions should not use the patch 		<ul style="list-style-type: none"> ▪ Nasal/throat irritation may be bothersome ▪ Dependence can result ▪ 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"> ▪ 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 (see PRECAUTIONS, above) 	<ul style="list-style-type: none"> ▪ May induce nausea in up to one third of patients ▪ Post-marketing surveillance data not yet available
WEB-SITE	www.nicorette.com	www.commitlozenge.com	www.nicodermcq.com	www.habitrol.com	www.nicotrol.com	www.nicotrol.com	---	www.chantix.com
COST/DAY ⁴	2 mg: \$2.53–\$5.16 (9 pieces) 4 mg: \$3.18–\$5.81 (9 pieces)	2 mg: \$4.98 (9 pieces) 4 mg: \$5.31 (9 pieces)	\$3.39–\$3.93 (1 patch)	\$2.10–\$2.94 (1 patch)	\$3.67 (8 doses)	\$5.25–\$6.07 (6 cartridges)	\$3.62–\$5.24 (2 tablets)	\$4.00–\$4.22 (2 tablets)

¹ 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.

² Marketed by GlaxoSmithKline.

³ Marketed by Pfizer.

⁴ Average wholesale price from 2006 Drug Topics Redbook. Montvale, NJ: Medical Economics Company, Inc., August 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.

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