



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 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 ▪ 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

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	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 might delay weight gain ▪ Patients can titrate therapy to manage withdrawal symptoms 	<ul style="list-style-type: none"> ▪ Lozenge use might satisfy oral cravings ▪ Lozenge use might delay weight gain ▪ 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 more 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 	<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: \$3.28–\$6.57 (9 pieces) 4 mg: \$4.31–\$6.57 (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)

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 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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