

Pharmacologic Product Guide: FDA-Approved Medications for Smoking Cessation

Nicotine Replacement Therapy (NRT) Formulations

	Gum	Lozenge	Transdermal Patch	Nasal Spray	Bupropion SR	Varenicline
Product	Nicorette¹, Generic OTC 2 mg, 4 mg original, cinnamon, fruit, mint (various)	Nicorette¹, Generic; Nicorette¹ Mini OTC 2 mg, 4 mg cinnamon, cherry, mint	Habitrol², NicoDerm CQ¹, Generic OTC 7 mg, 14 mg, 21 mg (24-hr release)	Nicotrol NS3 Rx Metered spray 10 mg/mL nicotine solution	Generic (formerly Zyban) Rx 150 mg sustained-release tablet	Generic (formerly Chantix³) 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 Pregnancy⁴ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy⁴ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy⁴ and breastfeeding Adolescents (<18 years) 	<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 Pregnancy⁴ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Concomitant therapy with medications/conditions known to lower the seizure threshold Hepatic impairment Pregnancy⁴ and breastfeeding Adolescents (<18 years) Treatment-emergent neuropsychiatric symptoms⁵ 	<ul style="list-style-type: none"> Severe renal impairment (dosage adjustment is necessary) Pregnancy⁴ and breastfeeding Adolescents (<18 years) Treatment-emergent neuropsychiatric symptoms⁵
Dosing	<p><i>1st cigarette ≤ 30 minutes after waking: 4 mg</i></p> <p><i>1st cigarette > 30 minutes after waking: 2 mg</i></p> <p>Weeks 1–6: 1 piece q 1–2 hours*</p> <p>Weeks 7–9: 1 piece q 2–4 hours*</p> <p>Weeks 10–12: 1 piece q 4–8 hours*</p> <p>*while awake</p> <ul style="list-style-type: none"> Maximum, 24 pieces/day During initial 6 weeks of treatment, use at least 9 pieces/day Chew each piece slowly Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) Resume chewing when tingle fades Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) Park in different areas of mouth 	<p><i>1st cigarette ≤ 30 minutes after waking: 4 mg</i></p> <p><i>1st cigarette > 30 minutes after waking: 2 mg</i></p> <p>Weeks 1–6: 1 lozenge q 1–2 hours*</p> <p>Weeks 7–9: 1 lozenge q 2–4 hours*</p> <p>Weeks 10–12: 1 lozenge q 4–8 hours*</p> <p>*while awake</p> <ul style="list-style-type: none"> Maximum, 20 lozenges/day During initial 6 weeks of treatment, use at least 9 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><i>>10 cigarettes/day:</i> 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks</p> <p><i><10 cigarettes/day:</i> 14 mg/day x 6 weeks 7 mg/day x 2 weeks</p> <ul style="list-style-type: none"> Rotate patch application site daily; do not apply a new patch to the same skin site for at least 1 week May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime); before recommending, rule out other factors that might be contributing (e.g., drug interaction between caffeine and tobacco smoke, other medications, and lifestyle factors) Duration: 8–10 weeks Local skin reactions (erythema, pruritus, burning) Sleep disturbances (abnormal or vivid dreams, insomnia); associated with nocturnal nicotine absorption 	<p>1–2 doses/hour* (8–40 doses/day)</p> <p>One dose = 2 sprays (1 in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa</p> <p>*while awake</p> <ul style="list-style-type: none"> Maximum -5 doses/hour or -40 doses/day During initial 6–8 weeks of treatment, use at least 8 doses/day Gradually reduce daily dosage over an additional 4–6 weeks Do not sniff, swallow, or inhale through the nose as the spray is being administered Duration: 12 weeks Nasal and/or throat irritation (hot, peppery, or burning sensation) Ocular irritation/tearing Sneezing Cough 	<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/benzodiazepines MAO inhibitors in preceding 14 days; concurrent use of reversible MAO inhibitors <p>150 mg po q AM x 3 days, then 150 mg po bid</p> <ul style="list-style-type: none"> Do not exceed 300 mg/day Begin therapy 1–2 weeks prior to quit date Allow at least 8 hours between doses Avoid bedtime dosing to minimize insomnia Duration: 7–12 weeks, with maintenance up to 6 months in selected patients Dose tapering is not necessary 	<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"> Begin therapy 1 week prior to quit date Take each dose after eating and with a full glass of water Dosing adjustment is necessary for patients with severe renal impairment Duration: 12 weeks; an additional 12-week course may be used in selected patients May initiate up to 35 days before target quit date OR may reduce smoking over a 12-week period of treatment prior to quitting and continue treatment for an additional 12 weeks



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Adverse Effects	<ul style="list-style-type: none"> No food or beverages 15 minutes before or during use Duration: up to 12 weeks Mouth and throat irritation Jaw muscle soreness Hiccups GI complaints (dyspepsia, nausea) May stick to dental work Adverse effects more commonly experienced when chewing the lozenge or using incorrect gum chewing technique (due to rapid nicotine release): <ul style="list-style-type: none"> -Lightheadedness/dizziness -Nausea/vomiting -Hiccups -Mouth and throat irritation 	<ul style="list-style-type: none"> GI complaints (dyspepsia, nausea) Might serve as an oral substitute for tobacco Might delay weight gain Can be titrated to manage withdrawal symptoms Can be used in combination with other agents to manage situational urges Relatively inexpensive Need for frequent dosing can compromise adherence Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome 	<ul style="list-style-type: none"> Once-daily dosing associated with fewer adherence problems Of all NRT products, its use is least obvious to others Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours Relatively inexpensive When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis) 	<ul style="list-style-type: none"> Can be titrated to rapidly manage withdrawal symptoms Can be used in combination with other agents to manage situational urges Need for frequent dosing can compromise adherence Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease Cost of treatment 	<ul style="list-style-type: none"> Insomnia Dry mouth Nausea Anxiety/difficulty concentrating Constipation Tremor Rash Seizures (risk is 0.15%) Neuropsychiatric symptoms (rare; see PRECAUTIONS) Twice-daily oral dosing is simple and associated with fewer adherence problems Might delay weight gain Might be beneficial in patients with depression Can be used in combination with NRT agents Relatively inexpensive (generic formulations) Seizure risk is increased Several contraindications and precautions preclude use in some patients (see PRECAUTIONS) Patients should be monitored for potential neuropsychiatric symptoms⁵ (see PRECAUTIONS) 	<ul style="list-style-type: none"> Nausea Sleep disturbances (insomnia, abnormal/vivid dreams) Headache Flatulence Constipation Taste alteration Neuropsychiatric symptoms (rare; see PRECAUTIONS) Twice-daily oral dosing is simple and associated with fewer adherence problems Offers a different mechanism of action for patients who have failed other agents Most effective cessation agent when used as monotherapy Patients should be monitored for potential neuropsychiatric symptoms⁵ (see PRECAUTIONS) Cost of treatment
Advantages	<ul style="list-style-type: none"> Might serve as an oral substitute for tobacco Might delay weight gain Can be titrated to manage withdrawal symptoms Can be used in combination with other agents to manage situational urges Relatively inexpensive 	<ul style="list-style-type: none"> Need for frequent dosing can compromise adherence Might be problematic for patients with significant dental work Proper chewing technique is necessary for effectiveness and to minimize adverse effects Gum chewing might not be acceptable or desirable for some patients 	<ul style="list-style-type: none"> Need for frequent dosing can compromise adherence Might be problematic for patients with significant dental work Proper chewing technique is necessary for effectiveness and to minimize adverse effects Gum chewing might not be acceptable or desirable for some patients 	<ul style="list-style-type: none"> Need for frequent dosing can compromise adherence Might be problematic for patients with significant dental work Proper chewing technique is necessary for effectiveness and to minimize adverse effects Gum chewing might not be acceptable or desirable for some patients 	<ul style="list-style-type: none"> Need for frequent dosing can compromise adherence Might be problematic for patients with significant dental work Proper chewing technique is necessary for effectiveness and to minimize adverse effects Gum chewing might not be acceptable or desirable for some patients 	<ul style="list-style-type: none"> Need for frequent dosing can compromise adherence Might be problematic for patients with significant dental work Proper chewing technique is necessary for effectiveness and to minimize adverse effects Gum chewing might not be acceptable or desirable for some patients
Cost/Day⁶	2 mg or 4 mg: \$2.52–\$3.42 (9 pieces)	2 mg or 4 mg: \$3.42–\$3.87 (9 pieces)	\$1.82–\$2.61 (1 patch)	\$10.63 (8 doses)	\$0.54 (2 tablets)	\$11.18 (2 tablets)

¹Marketed by GlaxoSmithKline.

²Marketed by Dr. Reddy's.

³Marketed by Pfizer. Chantix (0.5 mg and 1 mg tablets), formerly marketed by Pfizer, was voluntarily recalled (unavailable since 9/16/2021) due to the presence of N-nitroso-varenicline at or above the FDA acceptable intake limit. Alternative suppliers have been approved for generic formulations in the U.S.

⁴The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant tobacco users should be offered behavioral counseling interventions that exceed minimal advice to quit.

⁵In July 2009, the FDA mandated that the prescribing information for all bupropion- and varenicline-containing products include a boxed warning highlighting the risk of serious neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide. Clinicians should advise patients to stop taking varenicline or bupropion SR and contact a health care provider immediately if they experience agitation, depressed mood, or any changes in behavior that are not typical of nicotine withdrawal, or if they experience suicidal thoughts or behavior. If treatment is stopped due to neuropsychiatric

symptoms, patients should be monitored until the symptoms resolve. Based on results of a mandated clinical trial, the FDA removed this boxed warning in December 2016.

⁶Approximate cost based on the recommended initial dosing for each agent and average wholesale acquisition prices for generic and brand formulations from Red Book Online. Thomson Reuters, January 2024.

Abbreviations: MAO, monoamine oxidase; NRT, nicotine replacement therapy; OTC, over-the-counter (nonprescription product); Rx, prescription product.

For complete prescribing information and a comprehensive listing of warnings and precautions, please refer to the

manufacturers' package inserts.

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