## FIRST-LINE FDA-APPROVED TOBACCO CESSATION MEDICATIONS<sup>a</sup>



	Medication	Precautions <sup>c</sup>	Adverse Effects	Dosage	Use	ļ	Availability	Cost/day <sup>b</sup>
nulations	Nicotine Gum	Pregnancy (Category D) and breastfeeding Recent (≤2 weeks) myocardial infarction Serious underlying arrhythmias Serious/worsening angina pectoris Temporomandibular joint disease Caution with dentures Adolescents (<18 years)	Mouth/jaw soreness     Dyspepsia     Hiccups     Hypersalivation     Effects associated with incorrect chewing technique:     Lightheadedness     Nausea/Vomiting     Throat & mouth irritation	1st cigarette ≤30 minutes after waking: 4mg     1st cigarette >30 minutes after waking: 2mg     Use 1 piece every 1-2 hours     Maximum, 24 pieces/day     Park between cheek & gum upon tingling sensation (15-30 chews).     Repeat when tingle fades. Park on other side.	Up to 12 weeks Longer if desired, with provider approval. Do not eat or drink 15 minutes before or during use.	vered	Nicorette®, Nicorette Mint®, generic products (OTC only) 2mg, 4mg Original, Mint, Cinnamon, and Fruit	2 mg or 4 mg: \$1.90-\$5.49 (9 pieces)
Form	Nicotine Lozenge or Mini- Lozenge	Pregnancy and breastfeeding-not evaluated by the FDA     Recent (≤2 weeks) myocardial infarction     Serious underlying arrhythmias     Serious/worsening angina pectoris     Adolescents (<18 years)	Hiccups     Heartburn     Nausea     Headache (on 4mg)      Cough (on 4mg)     Hypertension     Flatulence     Insomnia	1st cigarette ≤30 min after waking: 4mg     1st cigarette >30 min after waking: 2mg     0se 1 lozenge every 1-2 hours, Maximum 20 pieces/day.     Allow to dissolve between cheek & gum.     Do not chew or swallow. Occasionally rotate to different areas of mouth.	approval.  Do not eat or drink 15 minutes before or during use.	IC or Rx if	Commit™ Lozenge, Nicorette Mini Lozenge, generic products (OTC) 2mg, 4mg Cherry, Cinnamon, Mint	2 mg or 4 mg: \$2.97-\$4.23 (9 pieces)
Nicotine Replacement Therapy (NRT)	Nicotine Patch	Pregnancy (Category D) and breastfeeding     Recent (≤2 weeks) myocardial infarction     Serious underlying arrhythmias     Serious/worsening angina pectoris     Adolescents (<18 years)	Local skin reaction     Sleep disturbances     Insomnia     Abnormal/vivid dreams     Headache	One patch per day (hairless site) If >10 cigs/day: 21mg 4-6 wks, 14mg 2-4 wks, 7mg 2-4 wks If <10/day: 14mg 6 wks, then 7mg 2 wks	8-12 Weeks     Longer if desired with provider approval. May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime).		Nicoderm CQ®, Nicotrol, generic products (Rx and OTC). 7 mg, 14 mg, 21 mg (24-hr release)	\$1.52–\$3.49 (1 patch)
	Nicotine Nasal Spray	Severe reactive airway disease Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) Pregnancy (Category D) and breastfeeding Recent (<2 weeks) myocardial infarction Serious underlying arrhythmias Serious/worsening angina pectoris Adolescents (<18 years)	Nasal and/or throat irritation (hot, peppery, or burning sensations, typically, only for a few initial days of use)      Rhinitis     Tearing     Sneezing     Cough     Headache	1-2 doses/hour (8-40 doses/day) (one dose= one spray per nostril)     Maximum: 5 doses/hr     Patients should not sniff, swallow, or inhale through the nose as the spray is being administered.     On average 100 doses per bottle.	• 3-6 months		Nicotrol NS® (prescription only)	\$9.64 (8 doses)
Nic	Nicotine Oral Inhaler	Recent (≤2 weeks) myocardial infarction     Serious underlying arrhythmias     Serious/worsening angina pectoris     Bronchospastic disease (respiratory disease)     Pregnancy (Category D) and breastfeeding     Adolescents (<18 years)	Local irritation of mouth & throat (typically, for only a few initial days of use)     Cough     Rhinitis     Hiccups     Dyspepsia     Headache	6-16 cartridges/day. Individualize dosing; initially use 1 cartridge q 1-2 hours. Nicotine in cartridge is used up after about 20 min of continuous puffing. Puffing on the Inhaler for 5 min. at a time will give enough nicotine for 4 uses. Do not inhale into the lungs, but instead use short, quick puffs.	Up to 6 months Taper dosage during final 3 months. Keep in temp of 40° F or higher. Do not eat or drink 15 minutes before or during use.	Prescription (Rx) only	Nicotrol® Inhaler (prescription only) 10mg cartridge delivers 4mg inhaled nicotine vapor.	\$16.38 (6 cartridges)
Non-Nicotine Medications®	Bupropion SR	Concomitant therapy with medications known to lower the seizure threshold Hepatic impairment     Pregnancy (Category C) and breastfeeding     Adolescents (<18 years)     Treatment-emergent neuropsychiatric symptoms: Boxed warning removed December 2016 <sup>d</sup> Contraindications:     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 during preceding 14 days; concurrent use of reversible MAO inhibitors	Sleep disturbance (vivid dreams, insomnia) Dry mouth Rash Nervousness Nausea, dizziness Constipation Seizures (risk 1/1,000) [0.1%] Patients should be monitored for potential neuropsychiatric symptoms (rare)	Days 1-3: 150 mg P.O. each morning Days 4-end: 150 mg twice daily Allow at least 8 hours between doses. Avoid bedtime dosing to minimize insomnia. Dose tapering is not necessary. Can be used safely with NRT.	Begin treatment 1-2 weeks before quit date.     Use for 7-12 weeks or maintenance up to 6 months. Don't take extra dose to make up for missed dose.		Generic (formerly Zyban®) (prescription only) 150 mg sustained-release tablet	\$0.72 (2 tablets)
Non-Nicotine	Varenicline	Severe renal impairment (dosage adjustment is necessary) Pregnancy (Category C) and breastfeeding Adolescents (<18 years) Treatment-emergent neuropsychiatric symptoms: Boxed warning removed December 2016 <sup>d</sup>	Nausea/Vomiting Sleep disturbances Insomnia Abnormal/vivid dreams Constipation Flatulence Patients should be monitored for potential neuropsychiatric symptoms (rare)	Days 1-3: 0.5 mg P.O. every morning Days 4-7: 0.5 mg twice daily Days 8-end: 1 mg twice daily Take dose after eating with a full glass of water. Dose tapering is not necessary.	Begin treatment one week before quit date. Dosing adjustments are necessary for patients with severe renal impairment. May initiate up to 35 days before target quit date. May reduce smoking over 12-wk period of treatment prior to quitting and continue treatment for an additional 12 weeks. Use for 3 months; maintenance up to 6 months.		Chantix <sup>™</sup> , generic (prescription only) .5mg, 1mg tablet	\$16.17 <sup>b</sup> - \$17.20 (2 tablets)

a The information contained in this table is not comprehensive and some information may have changed since release. Please see package insert for additional information.
b Approximate cost/day based on wholesale acquisition cost from Red Book Online. Thomson Reuters, September 2021. The \$16.17 cost for generic Varenicline based on one national pharmacy chain in November 2021.
c Quitting smoking, with or without medication, can result in nicotine withdrawal symptoms (such as depressed mood, agitation) or a worsening of underlying psychiatric illness, such as depression. Monitor patients for behavior or mood changes.
d In July 2009, FDA mandated that the prescribing information for all buproprion – and varenicline-containing products include a black-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 healthcare 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, FDA removed this boxed warning in December 2016.

e Other prescription medications, such as nortriptyline or clonidine are not FDA approved for smoking cessation, but may be utilized for this purpose.

\*Adapted from: Fiore MC, Jaén CR, Baker TB, et al. Treating Tobacco Use and Dependence: 2008 Update. Quick Reference Guide for Clinicians. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. April 2009. Smoking Cessation: A Report from the Surgeon General Table 6.2. January 2020.