

FDA-Approved Smoking Cessation Medications

1st line Medications for Tobacco Cessation Treatment*

Drug (Available Doses)	How Sold (U.S.)	Dosing Instructions†	Administration	Common Side Effects	Advantages	Disadvantages
Nicotine patch 21 mg 14 mg 7 mg	OTC or Rx	Starting dose: 21 mg for ≥10 cigarettes per day. 14 mg for <10 cigarettes per day. After 6 weeks, option to taper to lower doses for 2-6 weeks. Use ≥3 months. After 6 weeks, continue original dose or taper to lower doses (either option acceptable).	Apply a new patch each morning to dry skin. Rotate application site to avoid skin irritation. May start patch before or on quit date. Keep using even if a slip occurs. If insomnia or disturbing dreams, remove patch at bedtime.	Skin irritation Trouble sleeping Vivid dreams (patch can be removed at bedtime to manage insomnia or vivid dreams)	Easiest nicotine product to use. Provides a steady nicotine level. Combination NRT therapy: Can add prn gum, lozenge, inhaler, or nasal spray to patch to cover situational cravings.	User cannot alter dose if cravings occur during the day.
Nicotine lozenge 4 mg 2 mg	OTC or Rx	If 1st cigarette is ≤30 minutes of waking: 4 mg. If 1st cigarette is >30 minutes of waking: 2 mg. Use ≥3 months.	Place between gum and cheek, let it melt slowly. Use 1 piece every 1-2 hours (Max: 20/day).	Mouth irritation Hiccups Heartburn Nausea	User controls nicotine dose. Oral substitute for cigarettes. May be added to patch to cover situational cravings. Easier to use than gum for those with dental work or dentures.	No food or drink 15 minutes prior to use and during use.
Nicotine gum 4 mg 2 mg	OTC or Rx	If 1st cigarette is ≤30 minutes of waking: 4 mg. If 1st cigarette is >30 minutes of waking: 2 mg. Use ≥3 months.	Chew briefly until mouth tingles, then 'park' gum inside cheek until tingle fades. Repeat chew-and-park each time tingle fades. Discard gum after 30 minutes of use. Use ~ 1 piece per hour (Max: 24/day).	Mouth irritation Jaw soreness Heartburn Hiccups Nausea	User controls nicotine dose. Oral substitute for cigarettes. May be added to patch to cover situational cravings.	Not chewed in same way as regular gum; requires careful instruction. Can damage dental work and be difficult to use with dentures. No food or drink 15 minutes prior to use and during use.
Nicotine inhaler 10-mg cartridge	Rx only	10 mg/cartridge. Each cartridge has ~80 puffs. Use ≥3 months.	Puff into mouth/ throat until cravings subside. Do not inhale into lungs. Change cartridge when nicotine taste disappears. Use 1 cartridge every 1-2 hours (Max: 16/day).	Mouth and throat irritation Coughing if inhaled too deeply	User controls nicotine dose. Mimics hand-to-mouth ritual of smoking cigarettes. May be added to patch to cover situational cravings.	Frequent puffing required.
Nicotine nasal spray 10 mg/ml (10 ml bottle)	Rx only	10 mg/ml. 0.5 mg per spray. Each bottle has ~200 sprays. Use ≥3 months.	Use 1 spray to each nostril. Use spray every 1-2 hours. (Max: 80/day).	Nasal and throat irritation Rhinitis Sneezing Coughing Tearing	User controls nicotine dose. Most rapid delivery of nicotine among all NRT products. May be added to patch to cover situational cravings.	Has the most side effects of all NRT products. Some users cannot tolerate local irritation to nasal mucosa.
Varenicline (tablet) 0.5 mg 1.0 mg	Rx only	Days 1-3: 0.5 mg/day. Days 4-7: 0.5 mg twice a day. Day 8+: 1 mg twice a day. Use 3-6 months.	Start 1-4 weeks before quit date. Take with food and a tall glass of water to minimize nausea.	Nausea Insomnia Vivid dreams Headache	Quit date can be flexible, from 1 week to 3 months after starting drug. Dual action: relieves nicotine withdrawal and blocks reward of smoking. Oral agent (pill).	Because of previous FDA boxed warning (now removed), many patients fear psychiatric adverse events, even though they are no more common than with other cessation medications.
Bupropion sustained release (SR) (tablet) 150 mg	Rx only	150 mg/day for 3 days, then 150 mg twice a day. Use 3-6 months.	Start 1-2 weeks before quit date.	Insomnia Agitation Dry mouth Headache	May lessen post-cessation weight gain while drug is being taken. Oral agent (pill).	Increases seizure risk: not for use if seizure disorder or binge drinking.

*All are FDA-approved as smoking cessation aids and listed as a 1st line medication by U.S. Clinical Practice Guidelines (Fiore, 2008)

†Recommended duration of use for medications is at least 3 months, but extending dose to 6 months is frequently done to prevent relapse to tobacco use. Patch dosing differs slightly from FDA labeling.

FDA = U.S. Food and Drug Administration; NRT = nicotine replacement therapy; OTC = over the counter (no prescription required); Rx = prescription required.