

Varenicline

- Updated 2011 Mar 10 12:17:00 PM: 1 trial found evaluating varenicline for smokeless tobacco cessation in Cochrane review (Cochrane Database Syst Rev 2011 Feb 16)
- varenicline appears effective for smoking cessation at 6–12 months and more effective than bupropion (Cochrane Database Syst Rev 2011 Feb 16) [view update](#)
- varenicline may increase continuous abstinence rates in patients using smokeless tobacco who want to quit (BMJ 2010 Dec 6) [view update](#)

Related Summaries:

- [Tobacco use disorder](#)
- [Counseling for tobacco cessation](#)
- [Bupropion for smoking cessation](#)
- [Nicotine replacement therapy for smoking cessation](#)

Overview:

- varenicline tartrate (Chantix) FDA approved for smoking cessation
- varenicline is nicotinic receptor partial agonist which reduces withdrawal symptoms and blocks nicotine effects from smoking
- varenicline may be associated with serious neuropsychiatric symptoms, including changes in behavior, agitation, depressed mood, suicidal ideation, and attempted and completed suicide
- varenicline may increase continuous abstinence rates and appears more effective than placebo, bupropion or transdermal nicotine ([level 2 \[mid-level\] evidence](#))
- varenicline increases continuous abstinence rates in patients with cardiovascular disease ([level 1 \[likely reliable\] evidence](#))
- start 1 week before target quit date
- dosing orally after eating with full glass of water
 - 0.5 mg once daily for 3 days
 - 0.5 mg twice daily for days 4–7
 - 1 mg twice daily for 11 weeks

- additional 12 weeks approved for patients with successful smoking cessation
- maximum dose 0.5 mg twice daily if severe renal impairment (creatinine clearance < 30 mL/minute), maximum dose 0.5 mg once daily on hemodialysis
- most common adverse effects in clinical trials were nausea (30%–40% patients), headache, vomiting, flatulence, insomnia, abnormal dreams, and dysgeusia
- Pregnancy Category C

▼ [Warnings](#)

Warnings:

Neuropsychiatric Symptoms and Suicide Risk

- Serious neuropsychiatric symptoms (e.g., depression, suicidal ideation, suicide attempt, completed suicide) have been reported in patients receiving varenicline for smoking cessation. [1](#) [10](#) [11](#) [12](#) [13](#) ([See Neuropsychiatric Symptoms and Suicidality under Cautions.](#))
- Such effects have occurred in patients with or without psychiatric illnesses. [1](#) [10](#) [11](#) [12](#) [13](#) Safety and efficacy of varenicline not established in patients with serious psychiatric illness (e.g., schizophrenia, bipolar disorder, major depressive disorder); such patients may experience recurrence or worsening of symptoms during varenicline therapy. [1](#) [10](#) [12](#)
- Depressed mood may be a symptom of nicotine withdrawal; however, some symptoms occurred in varenicline-treated patients who continued to smoke. [1](#)
- Most symptoms occurred during varenicline therapy, but some were reported following discontinuance of drug. [1](#) [10](#) [13](#)
- Monitor all patients receiving varenicline for neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, and suicide-related events (including ideation, behavior, and attempted suicide). [1](#) [10](#) [12](#)
- Patient should discontinue varenicline and immediately contact clinician if agitation, hostility, depressed mood, or changes in thinking or behavior not

typical for the patient occur, or if patient develops suicidal ideation or behavior.

[1](#) [10](#) [11](#) [13](#)

- Symptoms resolved upon drug discontinuance in many cases, but persisted in some. [1](#) [10](#) [12](#) Provide ongoing patient monitoring and supportive care until symptoms resolve. [1](#) [10](#)
- Weigh risks of varenicline therapy against benefits of its use for smoking cessation. [1](#) [7](#) [10](#) [13](#)