Chantix (varenicline) - Drug Summary

Pfizer Laboratories Div Pfizer Inc

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Chantix
(varenicline)

BOXED WARNING

Serious neuropsychiatric events including, but not limited to, depression, suicidal ideation, suicide attempt, and completed suicide reported. Some reported cases might have been complicated by nicotine withdrawal symptoms in patients who stopped smoking. Monitor for neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, and suicide-related events. Worsening of preexisting psychiatric illness and completed suicide reported in some patients attempting to quit smoking while on therapy. Advise patients and caregivers that the patient should stop taking therapy and contact a healthcare provider immediately if agitation, hostility, depressed mood, changes in behavior or thinking, suicidal ideation, or suicidal behavior occurs. Weigh risks against benefits of use.

THERAPEUTIC CLASS

Nicotinic acetylcholine receptor agonist

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Smoking Cessation Aid

Set quit date and start 1 week before quit date. Alternatively, may begin therapy and then quit smoking between Days 8 and 35 of treatment

Days 1-3: 0.5mg qd
Days 4-7: 0.5mg bid
Day 8-End of Treatment: 1mg bid
Treat for 12 weeks

If patient has successfully stopped smoking at end of 12 weeks, additional course of 12-week treatment is recommended to ensure long-term abstinence

If patient is motivated to quit and not successful in stopping smoking during prior therapy for reasons other than intolerability due to adverse events, or if relapse occurs after treatment, should make another attempt once factors contributing to failed attempt are identified and addressed

DOSING CONSIDERATIONS

Renal Impairment
Severe (CrCl <30mL/min):
Initial: 0.5mg qd
Titrate: May titrate prn to a max dose of 0.5mg bid

ESRD w/ Hemodialysis:
Max: 0.5mg qd if tolerated

Adverse Reactions
Consider a temporary/permanent dose reduction in patients who cannot tolerate adverse effects

ADMINISTRATION

Oral route

Take pc and w/ a full glass of water
Provide patients w/ appropriate educational materials and counseling to support the quit attempt

HOW SUPPLIED

Tab: 0.5mg, 1mg

WARNINGS/PRECAUTIONS

Seizures reported; caution w/ history of seizures or other factors that can lower the seizure threshold. Somnolence, dizziness, loss of consciousness, and difficulty concentrating reported; may impair physical/mental abilities. Cardiovascular (CV) events reported in patients w/ stable CV disease. Hypersensitivity reactions, including angioedema, and rare but serious skin reactions (eg, Stevens-Johnson syndrome, erythema multiforme) reported. Nausea reported; consider dose reduction for patients w/ intolerable nausea. Caution in elderly.

ADVERSE REACTIONS

N/V, headache, insomnia, somnolence, abnormal dreams, flatulence, constipation, dysgeusia, fatigue, upper respiratory tract disorder, abdominal pain, dyspepsia, dry mouth, sleep disorder, increased appetite.

DRUG INTERACTIONS

May increase intoxicating effects of alcohol. Nicotine replacement therapy (transdermal nicotine) may increase incidence of adverse events. Physiological changes resulting from smoking cessation may alter pharmacokinetics or pharmacodynamics of certain drugs (eg, theophylline, warfarin, insulin) for which dosage adjustment may be necessary.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Nicotinic acetylcholine receptor agonist; binds w/ high affinity and selectivity at α4β2 neuronal nicotinic acetylcholine receptors. The binding produces agonist activity while simultaneously preventing nicotine binding to these receptors.

PHARMACOKINETICS

Absorption: T_{max}=3-4 hrs. **Distribution:** Plasma protein binding (≤20%). **Metabolism:** Minimal. **Elimination:** Urine (92% unchanged); $T_{1/2}$=24 hrs.

ASSESSMENT

Assess for preexisting psychiatric illness, history of seizures or other factors that can lower the seizure threshold, CV disease, history of hypersensitivity to the drug, renal impairment, pregnancy/nursing status, and for possible drug interactions.

MONITORING

Monitor for neuropsychiatric symptoms or worsening of preexisting psychiatric illness, seizures, somnolence, dizziness, loss of consciousness, difficulty concentrating, CV events, skin reactions, hypersensitivity reactions, nausea, and other adverse reactions. Monitor renal function.

PATIENT COUNSELING

Inform about risks and benefits of treatment. Instruct to set a date to quit smoking and initiate treatment 1 week before quit date. Encourage to continue to attempt to quit even w/ early lapses after quit day. Encourage patients who are motivated to quit and who did not succeed in stopping smoking during prior therapy for reasons other than intolerability due to adverse events, or who relapsed after treatment to make another attempt w/ therapy once factors contributing to the failed attempt have been identified and addressed. Provide educational materials and necessary counseling to support attempt at quitting smoking. Instruct to notify physician if persistent nausea or insomnia develops. Advise to d/c and notify physician if agitation, hostility, depressed mood, or changes in behavior/thinking develop. Advise to notify physician prior to treatment of any history of psychiatric illness. Inform that quitting smoking may be associated w/ nicotine withdrawal symptoms or exacerbation of preexisting psychiatric illness. Advise to inform physician of any history of seizures or other factors that can lower seizure threshold; instruct patient to d/c treatment and contact physician immediately if seizure is experienced. Instruct patient to reduce amount of alcohol they consume while on therapy until they know whether therapy affects their tolerance for alcohol. Advise to use caution when driving or operating machinery until patients know how quitting smoking and/or therapy may affect them. Advise to notify physician if symptoms of new or worsening CV events develop and to seek immediate medical attention if signs/symptoms of a MI or stroke are experienced. Instruct to d/c and seek immediate medical care if angioedema or a skin reaction occurs. Inform that vivid, unusual, or strange dreams may occur. If patient is pregnant, planning to become pregnant, or breastfeeding, advise about the risks of smoking, the potential risks of therapy, and the benefits of smoking cessation.

STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F).

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