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FDA Drug Safety Communication: Chantix (varenicline) may increase the risk of certain cardiovascular adverse events in patients with cardiovascular disease

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Safety Announcement

[6-16-2011] The U.S. Food and Drug Administration (FDA) is notifying the public that the smoking cessation aid Chantix (varenicline) may be associated with a small, increased risk of certain cardiovascular adverse events in patients who have cardiovascular disease. This safety information will be added to the *Warnings and Precautions* section of the Chantix physician labeling. The patient Medication Guide will also be revised to inform patients about this possible risk.

FDA reviewed a randomized clinical trial of 700 smokers with cardiovascular disease who were treated with Chantix or placebo (see [Data Summary](#) below). In this trial, Chantix was effective in helping patients quit smoking and remain abstinent from smoking for as long as one year. Cardiovascular adverse events were infrequent overall, however, certain events, including heart attack, were reported more frequently in patients treated with Chantix than in patients treated with placebo.

Healthcare professionals should be aware that smoking is an independent and major risk factor for cardiovascular disease, and smoking cessation is of particular importance in this patient population. The known benefits of Chantix should be weighed against its potential risks when deciding to use the drug in smokers with cardiovascular disease.

Patients taking Chantix should contact their healthcare professional if they experience new or worsening symptoms of cardiovascular disease.

FDA is continuing to evaluate the cardiovascular safety of Chantix and is requiring the manufacturer to conduct a large, combined analysis (meta-analysis) of randomized, placebo-controlled trials. FDA will update the public when additional information is available.

Additional Information for Patients

- Smoking is a major risk factor for cardiovascular disease, and Chantix can help you quit smoking.
- If you have cardiovascular disease, taking Chantix may increase your risk of certain cardiovascular adverse events.
- Contact your healthcare professional if you experience new or worsening symptoms of cardiovascular disease while taking Chantix, for example:
 - Shortness of breath or trouble breathing
 - New or worsening chest pain
 - New or worse pain in legs when walking
- Read the Medication Guide you get along with your Chantix prescription. It explains the risks associated with the use of Chantix.
- Talk to your healthcare professional if you have questions or concerns about Chantix.
- Report side effects from the use of Chantix to the FDA MedWatch program, using the information in the "Contact Us" box at the bottom of the page.

Additional Information for Healthcare Professionals

- Smoking is an independent and major risk factor for cardiovascular disease, and Chantix is effective in helping patients quit smoking.
- Be aware that a small, increased risk of certain cardiovascular adverse events was reported in a study of patients with cardiovascular disease receiving Chantix. The events included angina pectoris, nonfatal myocardial infarction, need for coronary revascularization, and new diagnosis of peripheral vascular disease or admission for a procedure for the treatment of peripheral vascular disease.
- Weigh the known benefits of Chantix against the potential risks of its use in smokers with cardiovascular disease.
- Counsel patients to seek medical attention if they experience new or worsening symptoms of

cardiovascular disease while taking Chantix.

- Encourage patients to read the Medication Guide they receive along with their Chantix prescription.
- Report adverse events involving Chantix to the FDA MedWatch program using the information in the "Contact Us" box at the bottom of this page.

Data Summary

FDA reviewed a randomized, double-blind, placebo-controlled clinical trial designed to assess the efficacy and safety of Chantix for smoking cessation in 700 patients aged 35 to 75 years with stable, documented cardiovascular disease (other than, or in addition to, hypertension) that had been diagnosed at least two months prior to the screening visit. Patients were randomized to treatment with Chantix 1 mg twice daily (n=350) or placebo (n=350). The study consisted of a 12-week treatment period that was followed by a 40-week non-treatment period. Patients also received smoking cessation counseling throughout the study. The 4-week Continuous Quit Rate (CQR) for Weeks 9 through 12 was obtained through weekly reports of cigarette or other nicotine use since the last study visit, and confirmed by measurement of end-expiratory exhaled carbon monoxide ≤ 10 ppm.

The results showed a statistically significantly higher 4-week CQR in the Chantix arm compared with the placebo arm (47% versus 14%, respectively; $p < 0.0001$). The continuous abstinence rate from Week 9 through Week 52 of the study was also significantly higher in the Chantix group compared with the placebo group (19% versus 7%, respectively; $p < 0.0001$).

Certain cardiovascular adverse events were reported in more patients treated with Chantix than patients treated with placebo. These included angina pectoris, nonfatal myocardial infarction, need for coronary revascularization, and new diagnosis of peripheral vascular disease or admission for a procedure for the treatment of peripheral vascular disease, as is shown in the table below. These events were reviewed by an independent cardiovascular endpoint committee. Some of the patients requiring coronary revascularization underwent the procedure as part of management of nonfatal myocardial infarction and hospitalization for angina pectoris. The trial was not designed to have statistical power to detect differences between the arms on the safety endpoints.

Adjudicated Cardiovascular Events During the 52-Week Study Period ($\geq 1\%$ in any group)

	Varenicline N=353* n (%)	Placebo N=350 n (%)
Nonfatal myocardial infarction	7 (2.0)	3 (0.9)
Need for coronary revascularization†	8 (2.3)	3 (0.9)
Hospitalization for angina pectoris	8 (2.3)	8 (2.3)
New diagnosis of peripheral vascular disease (PVD) or admission for a procedure for the treatment of PVD	5 (1.4)	3 (0.9)

*Three patients in the varenicline arm did not meet the protocol-specified definition of stable cardiovascular disease but were included in the safety analysis population.


†Patients with need for coronary revascularization in the varenicline arm include 5 patients who are also counted under nonfatal myocardial infarction and/or hospitalization for angina pectoris events. Patients with need for coronary revascularization in the placebo arm include 2 patients who are also counted under nonfatal myocardial infarction and/or hospitalization for angina pectoris.

Related Information

- [Varenicline \(marketed as Chantix\) Information](#)

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