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Safety

Chantix (varenicline): Label Change - Risk of Certain Cardiovascular Adverse Events

[UPDATED 07/22/2011] FDA has approved an updated drug label for Chantix (varenicline) to include information about the efficacy and safety of the drug in two patient populations who may benefit greatly from giving up smoking—those with cardiovascular disease and those with chronic obstructive pulmonary disease (COPD). The updated label now also includes alternative directions for patients to select a quit smoking date.

[Posted 06/16/2011]

AUDIENCE: Family Medicine, Cardiology

ISSUE: FDA notified healthcare professionals and patients that the Prescribing Information for this drug product will be strengthened to inform the public that use of 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 and the patient Medication Guide.

BACKGROUND: FDA reviewed a randomized, double-blind, placebo-controlled clinical trial of 700 smokers with cardiovascular disease who were treated with Chantix or placebo. While cardiovascular adverse events were infrequent overall, certain events, including heart attack, were reported more frequently in patients treated with Chantix than in patients treated with placebo. 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. 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.

RECOMMENDATION: See the Data Summary section of the Drug Safety Communication for additional information.

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 are encouraged to read the Medication Guide they receive along with their Chantix prescription.

Healthcare professionals and patients are encouraged to report adverse events, side effects, or product quality problems related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm¹
- Download form² or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[07/22/2011 - Drug Safety Communication³ - FDA]

[06/16/2011 - Drug Safety Communication⁴ - FDA]

Previous MedWatch Alert:

[11/20/2007⁵]

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