

Stop-smoking drug Chantix may carry heart risks, FDA warns

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Smokers should talk with their doctor before taking the drug, agency says.

(HealthDay)—People who take the prescription quit-smoking drug Chantix may be at higher risk for cardiovascular problems, and doctors should weigh the risks of the drug against it benefits, the U.S. Food and Drug Administration said.

A major review of clinical trials that compared patients who took Chantix (<u>varenicline</u>) to patients who took a placebo found that those who took the drug had slightly higher rates of serious <u>cardiovascular</u> <u>events</u> such as nonfatal heart attack, nonfatal stroke and cardiovascular-related death, according to an FDA <u>drug safety</u> communication released Wednesday.

However, the increased risk among people taking Chantix was not statistically significant, which means that it is unclear whether their increased risk was due to the drug or due to chance, the agency added.



Chantix works by blocking the effects of nicotine on the brain. The FDA first alerted the public in June 2011 about the possible increased risk of <u>cardiovascular problems</u> associated with Chantix. The agency told <u>Pfizer Inc.</u>, the maker of Chantix, to conduct the data review to learn more about possible heart risks associated with the drug.

The new findings are similar to those in a clinical trial described in the FDA's June 2011 drug safety communication about Chantix. The warnings and precaution section of the Chantix label has been updated to include the results of the recent review, the FDA said.

For now, doctors should consider the risks and benefits of Chantix before prescribing it for patients. The agency noted that smoking is a major risk factor for heart disease, Chantix is effective in helping people to stop smoking, and quitting smoking brings immediate and significant health benefits.

Patients taking Chantix should contact their doctor if they develop new or worsening symptoms of cardiovascular disease, such as chest pain, shortness of breath, calf pain when walking, or sudden onset of weakness, numbness or difficulty speaking, the FDA said.

The agency also said that patients with questions or concerns about Chantix should talk to their doctor.

More information: The American Cancer Society offers a guide to quitting smoking.

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