SAMFORD UNIVERSITY GLOBAL DRUG INFORMATION SERVICE'S

NEW DRUG FAX SHEET

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POTENTIAL ALCOHOL – VARENICLINE (CHANTIX) INTERACTION

This special issue of *New Drug FAX Sheet* provides information from the FDA regarding a potential interaction between alcohol and varenicline. The verbatim safety alert can be found below. If you need further information, please contact the Samford University Global Drug Information Service at (205) 726-2659.

AUDIENCE: Family Practice, Patient, Pulmonology

ISSUE: FDA is warning that the prescription smoking cessation medicine Chantix (varenicline) can change the way people react to alcohol. Interactions between alcohol and Chantix have resulted in some patients experiencing increased intoxicating effects of alcohol, sometimes associated with aggressive behavior and/or amnesia. In addition, rare accounts of seizures in patients treated with Chantix have been reported. FDA has approved changes to the Chantix label to warn about these risks. Refer to the Drug Safety Communication for a detailed data summary.

BACKGROUND: Chantix is a prescription medicine that is FDA-approved to help adults quit smoking.

RECOMMENDATION: Healthcare professionals should weigh the potential risk of seizures against the potential benefits before prescribing Chantix in patients with a history of seizures or other factors that can lower the seizure threshold. Advise patients to immediately stop taking Chantix if they develop agitation, hostility, aggressive behavior, depressed mood, or changes in behavior or thinking that are not typical for them, or if they develop suicidal ideation or behavior.

Until patients know how Chantix affects their ability to tolerate alcohol, they should decrease the amount of alcohol they drink. Patients who have a seizure while taking Chantix should stop the medicine and seek medical attention immediately.

Also refer to the Drug Safety Communication for more information for patients and healthcare professionals.

Healthcare professionals and patients are encouraged to report adverse events or side effects 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
- Download form 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

Read the MedWatch Safety Alert, including links to the Press Release at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm437415.htm

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