



# DoD MEDICATION SAFETY NOTICE

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## Varenicline (Chantix)

On 21 May 2008, the Institute for Safe Medication Practice (ISMP) released a report on strong adverse safety signals associated with Chantix (varenicline). Varenicline is increasingly used across the country and within DoD in smoking cessation programs. Quoting from the recommendations in ISMP's report Executive Summary:

We have immediate safety concerns about the use of varenicline among persons operating aircraft, trains, buses and other vehicles, or in other settings where a lapse in alertness or motor control could lead to massive, serious injury. Other examples include persons operating nuclear power reactors, high-rise construction cranes or life-sustaining medical devices. Based on reports of sudden loss of consciousness, seizures, muscle spasms, vision disturbances, hallucinations, paranoia and psychosis, we believe varenicline may not be safe to use in these settings. The extent to which varenicline has already contributed to accidental death and injury has not yet been investigated because these adverse effects had not been previously reported. The Federal Aviation Administration approved varenicline for use by airline pilots before most of these reports were available. [On the day this report was released the FAA withdrew that approval.]

In addition, we recommend that patients and doctors exercise caution in the use of varenicline and consider the use of alternative approaches to smoking cessation.

Studies of varenicline prescriptions in military treatment facilities show increasing utilization from 262 prescriptions in FY 2006, when varenicline was first licensed for use, to 67,580 prescriptions in FY 2007. At the same time, Zyban (bupropion - another smoking cessation drug and not implicated in the ISMP study) use decreased from 37,261 to 23,975 prescriptions.

The safety and health of our men and women in uniform is paramount. Assisting with their desires to stop smoking is important wherever they are assigned and whatever their mission is. However, ensuring that they are given and use medications that do not put them and others at increased risk of injury or death is essential.

The Office of the Chief Medical Officer has reviewed the available material and, pending additional studies, **recommends** that:

- Varenicline should not be used by personnel operating aircraft (including aircrew and air traffic controllers) and missile crew members,
- Service smoking cessation programs should prepare and ensure wide use of information sheets for providers and patients on the risks and benefits of all drugs used in smoking cessation, to include varenicline,
- Adverse events for the smoking cessation drugs bupropion (Zyban) and varenicline (Chantix) should be reported to local facility P&T Committees, and
- The Pharmacovigilance Center, OTSG, U.S. Army, should prepare and disseminate a data collection tool for centralized submission and analysis of smoking cessation drug adverse events.

Additional recommendations for vehicle operators, operational personnel, and other DoD personnel are under consideration.

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