

# **MEDWATCH** The FDA Safety Information and **Adverse Event Reporting Program**

# FDA Drug Safety Communication: FDA updates label for stop smoking drug Chantix (varenicline) to include potential alcohol interaction, rare risk of seizures, and studies of side effects on mood,

#### behavior, or thinking

[Posted 03/09/2015]

FDA 提出警示, 戒菸藥品 varenicline(Chantix)可能改變服藥者對於酒精的反應, 酒精與 varenicline 併 用會增強酒醉反應,導致患者出現攻擊行為與健忘症狀,除此之外,也有少數服用 varenicline 後出現 癲癇的不良反應被通報。FDA 目前已核准廠商於說明書上註記上述風險。

#### 建議

FDA 建議,醫療人員在處方 varenicline 給有癲癇病史的病人前,或合併其它因素可能降低癲癇發作 閾值時,須衡量 varenicline 的治療效益與風險,並告知病人如果出現躁動、對他人有敵意、攻擊行為、 憂鬱、行為與思考模式上的改變或自殺傾向時,必須馬上停用 varenicline。

在病人得知服用 varenicline 對自身酒精耐受能力的影響程度前,服用 varenicline 期間必須減少酒精的 攝取量。若服藥期間出現癲癇症狀,必須馬上停藥並立即就醫。

[Posted 03/09/2015]

**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 guit 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.