

# Chantix – Is It Safe?

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# The Facts...

- 46 million smokers in the US (20.6% of adults)
- 26.5% of all Hoosiers smoke (2<sup>nd</sup> in the US behind West Virginia, per the newest report from the CDC)
- The cost? \$96 billion in direct annual costs, 443,000 annual premature deaths
- It takes smokers 6-10 attempts to quit
- Multiple short and long term benefits to quitting

# Chantix

- Competitively binds to  $\alpha 4\beta 2$  nicotinic receptors in the brain
- It exerts both partial agonist and antagonist effects
- In a pooled analysis of 2 major trials, the % of successful quitters was 44% for Chantix, c/w 30% for Zyban and 18% for placebo after 12 weeks of treatment

## Updated CHANTIX® (varenicline) USPI: Boxed Warning

### WARNING:

Serious neuropsychiatric events, including, but not limited to depression, suicidal ideation, suicide attempt and completed suicide have been reported in patients taking CHANTIX. Some reported cases may have been complicated by the symptoms of nicotine withdrawal in patients who stopped smoking. Depressed mood may be a symptom of nicotine withdrawal. Depression, rarely including suicidal ideation, has been reported in smokers undergoing a smoking cessation attempt without medication. However, some of these symptoms have occurred in patients taking CHANTIX who continued to smoke.

All patients being treated with CHANTIX should be observed for neuropsychiatric symptoms including changes in behavior, hostility, agitation, depressed mood, and suicide-related events, including ideation, behavior, and attempted suicide. These symptoms, as well as worsening of pre-existing psychiatric illness and completed suicide have been reported in some patients attempting to quit smoking while taking CHANTIX in the post-marketing experience. When symptoms were reported, most were during CHANTIX treatment, but some were following discontinuation of CHANTIX therapy.

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*Please see full Prescribing Information and  
Patient Medication Guide available at this presentation*

## Updated CHANTIX® (varenicline) USPI: Boxed Warning (Cont.)

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These events have occurred in patients with and without pre-existing psychiatric disease. Patients with serious psychiatric illness such as schizophrenia, bipolar disorder, and major depressive disorder did not participate in the pre-marketing studies of CHANTIX and the safety and efficacy of CHANTIX in such patients has not been established.

**Advise patients and caregivers that the patient should stop taking CHANTIX and contact a healthcare provider immediately if agitation, hostility, depressed mood, or changes in behavior or thinking that are not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior.** In many post-marketing cases, resolution of symptoms after discontinuation of CHANTIX was reported, although in some cases the symptoms persisted; therefore, ongoing monitoring and supportive care should be provided until symptoms resolve.

The risks of CHANTIX should be weighed against the benefits of its use. CHANTIX has been demonstrated to increase the likelihood of abstinence from smoking for as long as one year compared to treatment with placebo. The health benefits of quitting smoking are immediate and substantial.

*Please see full Prescribing Information and  
Patient Medication Guide available at this presentation* 23

## Updated Chantix USPI: Warning Section

- There have been reports of angioedema and hypersensitivity reactions following administration of Chantix. Pts need to seek immediate medical care if they experience these symptoms.

## Updated Chantix USPI: Warning Section

- There have also been reports of rare, but serious skin reactions, including Erythema Multiforme and Stevens-Johnson syndrome. Pts should stop Chantix and seek medical care if they have any muco-cutaneous symptoms.

# Updated Chantix USPI Precautions Section

- There have been reports of traffic accidents, near-miss incidents in traffic. Pts should use caution while driving or operating heavy machinery until they know how Chantix will affect them.
- May 23, 2008 -> FAA banned use of Chantix by pilots and FAA controllers

# Summary

- Smoking is highly addictive and it takes smokers at least 6-9 attempts to quit successfully
- We need to keep encouraging our patients to quit for the short- and long-term health benefits
- There are 7 FDA approved meds, including Chantix, to aid in tobacco cessation attempts.
- Don't be afraid to prescribe it! You should, however, counsel your pts about adverse side effects. If adverse effects occur, stop Chantix and try something else.