



December 10, 2007

Re: CHANTIX™ (varenicline) Package Insert update

Pfizer is committed to keeping health care providers abreast of the latest information regarding CHANTIX. CHANTIX is indicated as an aid to smoking cessation treatment in adults; it is the first non-nicotine prescription treatment option to become available in over a decade. CHANTIX has been prescribed to over 4 million patients in the United States since launch in July 2006.

Package Insert update

As of November 2007, Pfizer, in collaboration with the FDA, has made 3 updates to the CHANTIX labeling:

1. A new section entitled "Post-Marketing Experience" has been added to the Adverse Reaction section of the Package Insert based on recent postmarketing reports:

Post-Marketing Experience:

The following adverse events have been reported during post-approval use of Chantix. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

There have been reports of depressed mood, agitation, changes in behavior, suicidal ideation and suicide in patients attempting to quit smoking while taking Chantix. Smoking cessation with or without treatment is associated with nicotine withdrawal symptoms and the exacerbation of underlying psychiatric illness. Not all patients had known pre-existing psychiatric illness and not all had discontinued smoking. The role of Chantix in these reports is not known.

The Patient Information leaflet has also been updated to reflect this change.

In the controlled clinical trial program of more than 5000 subjects who received CHANTIX, adverse events related to psychiatric symptoms were captured and are reflected in the Package Insert. Specifically, suicidal ideation was rare and occurred at a rate comparable to that seen in subjects who received placebo. There were no suicides attributed to CHANTIX in our clinical trials. It's important to note that there is no scientific evidence establishing a causal relationship between CHANTIX and these reported events.

2. In May 2007, as a result of a small number of postmarketing reports, Pfizer updated the label to advise patients to use caution driving or operating machinery. As of the November 2007 label update, the statement has been modified slightly to read:

Patients should be advised to use caution driving or operating machinery until they know how quitting smoking with varenicline may affect them.

The Patient Information leaflet has also been updated to reflect this change.

3. For purposes of clarity, the copy regarding the side effect insomnia has been updated in the Patient Information leaflet to read:

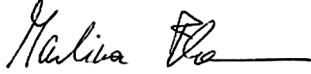
. . . sleep disturbance (trouble sleeping or vivid, unusual, or increased dreaming)

Impact of smoking

Smoking is the leading preventable cause of disease and premature death in the United States. According to the US Surgeon General's 2004 report *The Health Consequences of Smoking*, smoking causes a number of cancers, is a risk factor for cardiovascular disease, and harms nearly every organ in the body. One third of all tobacco users in this country will die prematurely from tobacco-related diseases, shortening their life span by an average of 13.2 years in men and 14.5 years in women (US Department of Health and Human Services). In the United States, more than 400,000 people die of smoking-related diseases each year.

We have enclosed the revised CHANTIX™ (varenicline) Package Insert for your information. For more information about CHANTIX, please visit www.pfizerpro.com/chantix or contact Pfizer Medical Information at **1-800-438-1985**. We hope you find this information helpful in understanding this subject so you can continue to appropriately treat your patients who want to quit smoking.

Sincerely,

A handwritten signature in black ink, appearing to read "Martina Flammer", with a horizontal line extending to the right.

Dr. Martina Flammer
Senior Medical Director
Pfizer Inc

Encl: Updated Package Insert