

Health Canada Endorsed Important Safety Information on  
CHAMPIX (varenicline tartrate)



2008-06-13

Dear Healthcare Professional,

**Subject: New safety information regarding CHAMPIX® (varenicline tartrate)**

Pfizer Canada in collaboration with Health Canada would like to notify healthcare professionals of important safety information regarding CHAMPIX, and post-marketing reports of serious neuropsychiatric adverse events, including depressed mood, agitation, hostility, changes in behaviour, suicidal ideation and suicide, as well as worsening of pre-existing psychiatric illness (previously diagnosed or not). Since the introduction of CHAMPIX in Canada, in April 2007 through April 30, 2008, a total of 226 Canadian cases of neuropsychiatric adverse events have been reported. For the same time period, there have been 708 534 prescriptions filled for CHAMPIX in Canada.<sup>1</sup>

- All patients attempting to quit smoking with CHAMPIX, their families and caregivers should be alerted about the need to monitor for symptoms of neuropsychiatric adverse events.
- Patients should be instructed to stop taking CHAMPIX and contact their healthcare provider immediately if they have or if their families or caregivers observe depressed mood, agitation, hostility or changes in behavior, that are not typical for the patient, or if the patient has suicidal ideation or suicidal behavior.
- **Patients with concomitant psychiatric conditions, even if well controlled, or with a history of psychiatric symptoms, should be diligently monitored.**

It is important to note that smoking cessation with or without treatment is associated with various symptoms. For example, dysphoric or depressed mood, insomnia, irritability, frustration, anger or hostility, anxiety, difficulty concentrating, restlessness, decreased heart rate, increased appetite or weight gain have been reported in patients attempting to stop smoking.

A number of confounding factors may have contributed to the serious neuropsychiatric symptoms reported in patients taking CHAMPIX. These include effects of nicotine withdrawal due to partial or complete smoking discontinuation; concomitant, or history of psychiatric conditions; and the concomitant use of other CNS drugs and/or alcohol. However, there are cases for which these confounding factors did not appear to be present, including cases where symptoms occurred within the first week of initiating CHAMPIX, and prior to initiating smoking cessation. There have been other cases where symptoms developed following cessation of CHAMPIX therapy.

Before taking CHAMPIX, patients are advised to tell their healthcare professional if they have experienced depression or other mental health problems. Patients and caregivers are advised that patients taking CHAMPIX should be instructed to stop taking CHAMPIX and to contact their healthcare provider immediately if they have or if their families or caregivers observe depressed mood, agitation, hostility or changes in behavior, that are not typical for the patient, or if the patient has suicidal ideation or suicidal behavior.

Patients with serious psychiatric illness such as schizophrenia, bipolar disorder, and major depressive disorder were excluded from the pre-marketing studies of CHAMPIX and the safety and efficacy of CHAMPIX in such patients have not been studied.

Managing marketed health product-related adverse reactions depends on healthcare professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse

reactions are generally presumed to underestimate the risks associated with health product treatments. 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.

The Canadian Product Monograph for CHAMPIX has recently been revised to reflect this important safety information. Health Canada issued an article concerning CHAMPIX in the Canadian Adverse Reaction Newsletter (CARN) in April 2008. This can be found at [www.hc-sc.gc.ca/dhp-mps/medeff/bulletin/carn-bcei\\_index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/bulletin/carn-bcei_index-eng.php). Any case of serious neuropsychiatric adverse reaction or other serious or unexpected adverse reactions in patients receiving CHAMPIX should be reported to Pfizer Canada Inc. or Health Canada at the following addresses:

Pfizer Canada Inc.  
17300 Trans-Canada Highway  
Kirkland, QC H9J 2M5  
1-800-463-6001  
<http://www.pfizer.ca>.

**Any suspected adverse reaction can also be reported to:**

Canada Vigilance Program  
Marketed Health Products Directorate  
HEALTH CANADA  
Address Locator: 0701C  
Ottawa, Ontario K1A 0K9  
Tel: (613) 957-0337 or Fax: (613) 957-0335  
To report an adverse reaction, consumers and health professionals may call toll free:  
Tel: 866-234-2345  
Fax: 866-678-6789  
[CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@hc-sc.gc.ca)

The [AR Reporting Form](#) and the [AR Guidelines](#) can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

[http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)  
[http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei\\_guide-ldir\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html)

**For other inquiries related to this communication, please contact Health Canada at:**

Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD)  
E-mail: [BGIVD\\_Enquiries@hc-sc.gc.ca](mailto:BGIVD_Enquiries@hc-sc.gc.ca)  
Tel: (613) 941-3207  
Fax: (613) 941-1183

Sincerely,

*original signed by*

Bernard Prigent, MD, MBA  
Vice-President and Medical Director  
Pfizer Canada Inc.

**Reference:** 1. IMS compuscript weekly (April 30, 2008).