

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



2008-06-13

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

CHAMPIX (varenicline tartrate) is one treatment option available to help quit smoking. Pfizer Canada in consultation with Health Canada is advising consumers of important safety information regarding CHAMPIX®. 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.¹

- A number of patients taking CHAMPIX have experienced unusual feelings of agitation, depressed mood, hostility, changes in behavior or impulsive or disturbing thoughts such as thoughts of self-harm or harm to others.
- Tell your doctor if you have experienced depression or other mental health problems before taking CHAMPIX as these symptoms may worsen while taking CHAMPIX.
- Stop taking CHAMPIX and tell your doctor right away if you, your family or caregiver noticed any of these symptoms, if you experienced these symptoms in a way that is not typical for you, or if you have thoughts of self-harm or harm to others.
- CHAMPIX has not been studied in people with mental health problems, and therefore your doctor will be monitoring you closely for new or worsened emotional or behavioral problems while on CHAMPIX.

Quitting smoking can also be associated with changes in mood and behaviour, with or without taking medication to help quit. A doctor or pharmacist should be consulted should these symptoms or those described above be experienced, since guidance has been provided to healthcare professionals on how to use CHAMPIX in patients, including those patients who may also have mental health problems.

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.

This information does not take the place of patients talking with their doctor/pharmacist about their condition or treatment. Patients, their family or caregiver are encouraged to speak with the doctor about any questions or concerns that they may have.

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. Any

case of serious change in mood or behavior 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

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/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

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).