

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
CIALIS[®], LEVITRA[®] and VIAGRA[®]



2006-05-31

Version Number 4

Subject: Association of the erectile dysfunction medication Cialis[®] (tadalafil), Levitra[®] (vardenafil hydrochloride) and Viagra[®] (sildenafil) with visual problem.

The manufacturers of Cialis[®], Levitra[®], Viagra[®], following discussions with Health Canada, would like to inform you of important safety information regarding a very small number of reports of serious visual problems in patients taking these medications.

- A very small number of men worldwide have reported visual problems and rarely lost eyesight in one eye after taking Cialis[®], Levitra[®] or Viagra[®].
- It has not been established whether these visual problems are related directly to the use of these medications or to other factors.
- If you are taking these medications and experience loss of vision, you should stop using the medication and have your eyes examined by a doctor as soon as possible.
- People who previously experienced a type of vision loss called Nonarteritic Anterior Ischemic Optic Neuropathy (NAION) may be at an increased risk of reoccurrence of NAION.

There have been rare reports of vision loss with the use of these erectile dysfunction medications. The vision loss may be partial or complete, affecting one or very rarely both eyes. While in some cases it may improve over time, it can also be irreversible. Those who experience one episode may be at greater risk of having a second episode in the other eye. The number of cases is small and most have occurred outside of Canada. As of October 31st, 2005, there have been 5 Canadian cases of visual problem that are possibly related to an erectile dysfunction medication.

Men who have erectile problems often have other conditions that put them at increased risk of NAION, including age greater than 50 years, heart disease, high blood pressure, high cholesterol, diabetes and certain pre-existing eye problems.

If you have questions about your current prescription, contact your physician or pharmacist.

A letter has been sent to Canadian physicians advising them of this safety information. This letter can be found on the Health Canada website at: http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2006/index_e.html.

This communication follows the earlier advisory issued by Health Canada on July 26, 2005 on the same issue.

Managing marketed health product-related adverse reactions depends on health care 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. Any case of serious visual problem or other serious or unexpected adverse reactions in patients receiving Cialis[®], Levitra[®] or Viagra[®] should be reported to their respective manufacturers or Health Canada at the following addresses:

For CIALIS[®]:

Consumer Response Centre
Eli Lilly Canada Inc.
3650 Danforth Avenue
Toronto, Ontario M1N 2E8
Tel: 1-888-545-5972
Fax: 1-888-898-2961

For LEVITRA[®]:

Drug Safety
Bayer Health Care
77 Belfield Road
Toronto, Ontario M9W 1G6
Tel: 1-800-265-7382
Fax: 1-866-232-0565

For VIAGRA[®]:

Pfizer Canada Inc.
Drug Safety
P.O. Box 800
Pointe-Claire-Dorval
Quebec, H9R 4V2
Tel: 1-800-463-6001
Fax: 1-514 426-7529

Any suspected adverse reaction can also be reported to:

Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
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

cadrmp@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/form/ar-ei_form_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:

Marketed Health Products Directorate

E-mail: MHPD_DPSC@hc-sc.gc.ca

Tel: (613) 954-6522

Fax: (613) 952-7738