

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



Bayer HealthCare



2006-06-02

Version Number 4

Dear Health Care Professional

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

The manufacturers of Cialis[®], Levitra[®] and Viagra[®], in consultation with Health Canada, would like to inform you of important safety information regarding the occurrence of serious visual disturbances in temporal association with the use of these medications. This communication follows the earlier Health Canada advisory of July 26, 2005 on the same issue.

- Sudden loss of vision has been reported in temporal association with the use of phosphodiesterase type 5 inhibitors (PDE5i), a class of medications used to treat erectile dysfunction. It is not clear whether these events are related directly to the use of PDE5 inhibitors or to other factors.
- Patients taking one of these erectile dysfunction medications who experience a temporary decrease or permanent loss of vision should stop taking the medication and be examined promptly.
- There may be an increased risk to patients who have already experienced a condition called Nonarteritic Anterior Ischemic Optic Neuropathy (NAION).

Phosphodiesterase type 5 inhibitors (PDE5i) are a class of medication used for the treatment of erectile dysfunction. There have been rare cases of vision loss, including NAION, reported post-marketing in temporal association with use of PDE5i. As of October 31st, 2005, there have been 5 Canadian cases of visual problems that may have been possibly related to an erectile dysfunction medication. However, a causal link between the use of Cialis[®], Levitra[®] or Viagra[®] and NAION could not be established. Individuals who have erectile dysfunction often have other conditions that put them at risk for NAION.

Clinically, NAION usually presents with a rapid onset of painless unilateral vision loss, often upon awakening¹. The vision loss may be partial or complete affecting one, or very rarely both eyes. While in some cases the condition may improve over time, it can also be irreversible. Involvement of the contralateral eye occurs in 12-19% of affected individuals within 5 years². Risk factors for NAION include: age greater than 50 years, heart disease, high blood pressure, high cholesterol, diabetes and certain pre-existing eye problems¹.

Patients who are prescribed PDE5i should be informed of the symptoms of NAION described above and advised to discontinue usage and seek medical attention promptly if vision loss develops. For patients who have had a prior episode of NAION, the potential risk of recurrence should be fully discussed before a prescription is issued.

Information about NAION has been incorporated in recent Product Monograph updates. You may wish to consult individual Product Monographs for detailed information.

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 vision loss 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[®]:

Customer 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: (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

Your professional commitment in this regard has an important role in protecting the well being of your patients by contributing to early signal detection and informed drug use. A copy of this letter is also available on the Health Canada website: http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2006/index_e.html.

Sincerely yours,

Loren D. Grossman, MD, FRCPC, FACP
Vice-President,
Research and Development
Eli Lilly Canada Inc.

Thomas P. Segerson M.D.
Vice-President,
Medical and Scientific Affairs
Bayer Inc.

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

A handwritten signature in blue ink, appearing to be 'Bernard Prigent', written over a horizontal line.

References:

1. Younge, BR. Optic Neuropathy, Anterior Ischemic. E-medicine. www.emdicine.com/oph/topic161.htm. Last updated February 7, 2005. Accessed 2005-06-27
2. Arnold Anthony, Ischemic Optic Neuropathy, Diabetic Papillopathy and Papillophlebitis, in Ophthalmology Second Edition, edited by Yanok and Duker, 2004