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## Drugs and Health Products

### Updated Safety Information for ZYPREXA\* (olanzapine) in Elderly Dementia Patients, Announced in Canada - Eli Lilly Canada Inc.

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Contact: [Bureau of Cardiology, Allergy and Neurological Sciences \(BCANS\)](#)

The Health Products and Food Branch (HPFB) posts on the Health Canada web site safety alerts, public health advisories, press releases and other notices as a service to health professionals, consumers, and other interested parties. These advisories may be prepared with Directorates in the HPFB which includes pre-market and post-market areas as well as market authorization holders and other stakeholders. Although the HPFB grants market authorizations or licenses for therapeutic products, we do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

This is duplicated text of a letter from **Eli Lilly Canada Inc.**  
Contact the company for a copy of any references, attachments or enclosures.

**Public Advisory**  
**Health Canada Endorsed Important Safety Information on**  
**ZYPREXA\* (olanzapine)**



Answers That Matter.

#### Subject: Updated Safety Information for ZYPREXA\* (olanzapine) in Elderly Dementia Patients, Announced in Canada

**Toronto, March 18, 2004** - Further to discussions with Health Canada, Eli Lilly Canada Inc. has recently informed [healthcare professionals](#) of new safety information on Zyprexa\* (olanzapine) concerning strokes and related events in elderly patients with dementia-related psychosis. Zyprexa is **not** approved for the treatment of elderly patients with dementia-related psychosis.

Information from five clinical studies in elderly patients with dementia-related psychosis showed that a higher proportion of patients taking Zyprexa experienced strokes or related events than did those who received placebo (sugar pill).

Please note that there is insufficient information to determine whether stroke in elderly patients with dementia-related psychosis is associated specifically with Zyprexa or all antipsychotic agents.

Patients are reminded of risk factors associated with an increased risk for stroke include previous history of stroke, high blood pressure, smoking, and medical conditions and/or medications that have an association with stroke. Generally, there is an increased risk of stroke and stroke-like events in the elderly population.

**Patients or their caregivers should immediately report to their healthcare professional any signs and/or symptoms of potential stroke such as sudden weakness or numbness in the face, arms, or legs, and/or speech or vision problems. Patients or their caregivers should inform their healthcare professional of their past and present medical history and should also consult their healthcare professional prior to making any changes to their medication.**

Information about this safety update has been sent to doctors and pharmacists to ensure they are aware of this new safety information when prescribing and dispensing Zyprexa. Eli Lilly Canada Inc. is working with Health Canada to update the Canadian Prescribing Information for Zyprexa.

Zyprexa is approved in Canada for the treatment of schizophrenia and related psychotic disorders and acute bipolar mania and to date, 13 million patients worldwide have been treated with Zyprexa for these approved treatments.

Inquiries from patients and healthcare professionals should be directed to the Eli Lilly Canada Customer Response Centre at 1-888-545-5972 between 8 a.m. and 6 p.m. EST. For media inquiries, please contact Kent Hovey-Smith, Eli Lilly Canada Inc. at (416) 693-3879.

**Any suspected adverse reactions in patients receiving Zyprexa (olanzapine) 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  
[cadrmc@hc-sc.gc.ca](mailto:cadrmc@hc-sc.gc.ca)

For other inquiries: please refer to contact information

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*.

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