



**PUBLIC ADVISORY**  
**Health Canada Endorsed Important Preliminary Safety**  
**Information Regarding REMINYL\* (galantamine)**

**Preliminary Safety Information from investigational studies with REMINYL\* (galantamine) in patients with mild cognitive impairment (MCI)**

Toronto, January 21, 2005 – Janssen-Ortho Inc., following discussions with Health Canada, is informing patients, caregivers and healthcare professionals of preliminary safety information from two investigational studies conducted with REMINYL in patients with mild cognitive impairment (MCI). REMINYL belongs to a class of drugs (cholinesterase inhibitors) used to treat Alzheimer's Disease.

In these two studies, about 1000 patients received REMINYL and about 1000 patients received placebo for two years.

REMINYL was not shown to be effective in patients with MCI. In addition, the initial analysis of both studies showed that 15 patients died during treatment with REMINYL compared to 5 patients during treatment with placebo (1.5% in REMINYL versus 0.5% in placebo). The causes of death were mainly cardiovascular or cerebrovascular in nature. It is unknown if other drugs of this class have a similar effect in MCI.

Janssen-Ortho, in cooperation with Health Canada, is currently completing the analyses of the data from these studies. Further information on the findings will be provided as soon as available.

**In Canada, REMINYL is approved only for the symptomatic treatment of patients with mild to moderate dementia of the Alzheimer's type. The use of REMINYL is not advised outside of its approved indication. Patients should be treated according to the approved Canadian prescribing information.**

No regulatory applications for the use of REMINYL in the treatment of mild cognitive impairment have been submitted anywhere in the world.

For more information, patients should consult their health care professional. Patients should NOT discontinue their medication without consulting their physician or pharmacist first.

This advisory can be accessed at Health Canada's web site at:

[http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index\\_advisories\\_public\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advisories_public_e.html)

This information is also available at:

[http://www.janssen-ortho.com/JOI/pdf\\_files/PublicAdvisory\\_En\\_reminyl.pdf](http://www.janssen-ortho.com/JOI/pdf_files/PublicAdvisory_En_reminyl.pdf)

Additional information is also available at <http://www.clinicalstudyresults.org/>

Janssen-Ortho Inc. is a research-based pharmaceutical company located in Toronto, Ontario.

For further information on Janssen-Ortho Inc.: Alexandra Gillespie, Janssen-Ortho Inc., (416) 449-9444. Or call the Janssen-Ortho Medical Information Department at 1-800-567-3331, from 9 a.m. to 5 p.m. Monday to Friday, EST.

The identification, characterization, and management of marketed health product-related adverse reactions are dependent on the active participation of health care professionals in adverse reaction reporting programmes. Any occurrences of prescribing or dispensing errors or other serious and/or unexpected adverse reactions in patients receiving REMINYL should be reported to Janssen-Ortho Inc. or Health Canada at the following addresses:

Janssen-Ortho Inc.  
19 Green Belt Drive  
Toronto, Ontario  
M3C 1L9  
Or call toll free at 1-800-567-3331  
Or email to [dsscan@joica.jnj.com](mailto:dsscan@joica.jnj.com)  
Or toll free fax to 1 866 767 5865

Any suspected adverse incident 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  
Local Tel: (613) 957-0337 or Local Fax: (613) 957-0335  
Toll Free Tel: (866) 234-2345 or Toll Free Fax: (866) 678-6789  
[cadrmp@hc-sc.gc.ca](mailto: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*.

[www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adverse\\_e.pdf](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adverse_e.pdf)  
[www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adr\\_guideline\\_e.pdf](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adr_guideline_e.pdf)

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