



PUBLIC ADVISORY

**Health Canada Endorsed Important Safety Information Regarding
Medication Errors Involving REMINYL* (galantamine
hydrobromide) and AMARYL[®] (glimepiride)**

Subject: Errors in prescribing and dispensing of the medication REMINYL (galantamine hydrobromide) and AMARYL[®] (glimepiride).

Toronto, December 21, 2004 – Janssen-Ortho Inc. and Aventis Pharma Inc., (collectively, “the Companies”) in consultation with Health Canada, have informed Canadian health care professionals of reports of prescribing and dispensing errors in the United States between REMINYL (galantamine hydrobromide), a Janssen-Ortho prescription medication for mild to moderate Alzheimer’s disease, and AMARYL[®] (glimepiride), an Aventis Pharma prescription medication for type 2 diabetes.

- **There have been errors in prescribing and dispensing of the medications REMINYL and AMARYL[®].**
- **These errors have led to adverse events including two reports of death.**
- **As patients or caregivers, you can help in avoiding such errors by:**
 - **asking your physician to repeat the name of any medicine he or she prescribes;**
 - **asking your physician or nurse to clearly write down the name of the medication so you have it when you go to the pharmacy;**
 - **requesting a product brochure for the medication where available from your physician;**
 - **asking your pharmacist to double-check that you have received the right medication;**
 - **reading any package inserts that accompany your prescriptions.**

The Companies are aware of 36 reports, of which 12 were confirmed, of prescriptions that were either incorrectly written, interpreted, labeled or filled due to the similarity in names between REMINYL and AMARYL[®]. These reports include instances in which REMINYL was prescribed but AMARYL[®] was incorrectly dispensed, leading to various adverse events including severe hypoglycemia (lowering of blood sugar). There were two reports of death subsequent to the medication error. To the Companies’ knowledge all reports originated in the US and the Companies are unaware of any reports of medication errors in Canada.

In order to raise awareness and to educate prescribers and pharmacists about these medication errors, The Companies are developing a communication program to help prevent medication prescribing and dispensing errors. The program includes outreach to pharmacists, physicians and patient associations through a variety of targeted communications.

These two products have an overlapping strength (4mg) and an overlapping dosage (tablets). In addition, both products have generic names (galantamine vs. glimepiride) that may lead to their storage in close proximity. It is important to note that REMINYL has a starting dosage of 4 mg TWICE a day, whereas AMARYL[®] is usually initiated at 1 mg ONCE daily.

The Companies have provided this information to physicians and pharmacists across Canada. This advisory and the letters issued to physicians and pharmacists can be accessed at Health Canada's web site at:

http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advisories_professionals_e.html

This information is also available at <http://www.janssen-ortho.com/> or <http://www.aventispharma.ca>. For more information, patients should consult their health care professional. Patients should NOT discontinue their medication without consulting their physician or pharmacist first. If you or your caregiver have questions about your current prescription, please talk to your doctor or take the pills back to your pharmacy and speak with your pharmacist.

As with all medications, REMINYL and AMARYL[®] should not be used by anyone who does not require the drug to treat a disease or its symptoms.

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

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.

For further information on Aventis Pharma Inc., please call Aventis Pharma Medical Information Department at 1-800-265-7927, from 9 a.m. to 5 p.m. Monday to Friday, EST. Media inquiries should be directed to Joëlle Sissmann, Aventis Pharma Inc., at (514) 956-4275.

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 or AMARYL[®] should be reported to Janssen-Ortho Inc. (for REMINYL), Aventis Pharma Inc. (for AMARYL[®]) 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
Or toll free fax to 1 866 767 5865

or

Aventis Pharma Inc.
2150 St. Elzear Blvd. West
Laval, Quebec
H7L 4A8
Call toll free at 1-800-265-7927
Or toll free fax to 1-800-268-3846

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

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
www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adr_guideline_e.pdf

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