November 18, 2014

Dear Healthcare Professional:

**Subject:** New safety information regarding the risk of serious skin reactions associated with the use of REMINYL® ER (galantamine hydrobromide)

Janssen Inc., in consultation with Health Canada, would like to provide you with important new safety information regarding the risk of serious skin reactions associated with the use of REMINYL® ER. This safety information also applies to generic versions of galantamine. A Public Communication (PC) to inform patients of this new safety information has also been posted on the Janssen Inc. website at [www.janssen.ca](http://www.janssen.ca) and on the Health Canada websites at [www.healthycanadians.gc.ca](http://www.healthycanadians.gc.ca).

REMINYL® ER is indicated for the symptomatic treatment of patients with mild to moderate dementia of the Alzheimer’s type. REMINYL® ER has not been studied in controlled clinical trials for longer than 6 months. REMINYL® ER should only be prescribed by (or following consultation with) clinicians who are experienced in the diagnosis and management of Alzheimer’s disease.

- Very rare cases of serious skin reactions including cases of Stevens-Johnson syndrome, acute generalized exanthematous pustulosis, and erythema multiforme have been reported in patients receiving REMINYL® ER.

- The WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS and CONSUMER INFORMATION sections of the REMINYL® ER Product Monograph have been updated to include this new safety information.

- Health care professionals should inform patients/caregivers about the signs of these serious skin reactions, and discontinue REMINYL® ER at the first appearance of skin rash.

The text of the WARNING AND PRECAUTIONS reads as follows:

**Skin**

*Serious skin reactions (Stevens-Johnson syndrome and acute generalized exanthematous pustulosis), and other less serious skin reactions (e.g., erythema multiforme), have been reported in patients receiving REMINYL® ER (see ADVERSE REACTIONS, Post-Market Adverse Drug Reactions). Patients or caregivers should be instructed to inform their health care provider of any skin reactions that occur during treatment with REMINYL® ER. It is recommended that treatment should be discontinued at the first appearance of skin rash.*
In addition, the Post-Market Adverse Drug Reactions and the Consumer Information Sections of the Product Monograph have been modified to include this new safety information. Please refer to the REMINYL® ER Product Monograph for details on these changes or the full prescribing information.

The current REMINYL® ER Product Monograph can be found at the Janssen Canada Web site (http://www.janssen.ca) and Health Canada’s Web page (http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp).

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. Cases of serious skin reactions (Stevens-Johnson syndrome and acute generalized exanthematous pustulosis), or other serious or unexpected adverse reactions in patients receiving REMINYL® ER should be reported to Janssen Inc. or Health Canada.

Drug Safety Department
Janssen Inc.
19 Green Belt Drive
Toronto, Ontario
M3C 1L9
Or call toll free at 1-866-825-7122
Or email to dsscan@joica.jnj.com
Or fax to 1-866-767-5865

To correct your mailing address or fax number email info@ptm-health.com or fax 1-888-780-4268.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:
• Calling toll-free at 1-866-234-2345
or
• Visiting MedEffect® Canada’s Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax

For other health product inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate
E-mail: mhpd_dpse.public@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Should you have any questions or require additional information, please contact Janssen Inc. Medical Information Department at 1-800-567-3331 or 1-800-387-8781 from 8:30 a.m. to 4:30 p.m. Monday to Friday Eastern Standard Time (EST).

Sincerely,

Cathy Lau, Ph.D.
Vice President
Regulatory Affairs and Quality Management

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