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Internet www.lundbeck.ca

Lundbeck Canada Inc.

July 15, 2015

Re: Updated Product Monograph of Ebixa®

Dear healthcare professional,

This letter, initiated voluntarily by Lundbeck Canada, is to inform you of the latest approval by Health Canada of the updated Product Monograph for Ebixa® (memantine hydrochloride). Ebixa® is a N-methyl-D-aspartate (NMDA) receptor antagonist indicated as monotherapy or as adjunctive therapy with cholinesterase inhibitors for the symptomatic treatment of patients with moderate to severe dementia of the Alzheimer's type.

This update to the Canadian Product Monograph of Ebixa concerns mainly the inclusion of new or updated safety information under the following sections:

WARNINGS AND PRECAUTIONS

HYPERSENSITIVITY

Skin Hypersensitivity Reactions - 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 Ebixa (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 Ebixa. It is recommended that treatment should be discontinued at the first appearance of skin rash.

POST-MARKET ADVERSE DRUG REACTIONS

A search of post-market data found cases of the following skin hypersensitivity reactions: drug eruption, pemphigoid, toxic skin eruption, Stevens-Johnson syndrome, skin exfoliation, blister, erythma multiforme, dermatitis bulous, pemphigus, acute generalized exanthematous pustulosis.

This revised Canadian Product Monograph of Ebixa® includes updated information under the following sections:

Warnings and Precautions
Other Adverse Events Observed During Clinical Trials
Post-Market Adverse Drug Reactions
Dosage and Administration
Consumer Information

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Please refer to the full updated Canadian Product Monograph that can be found on Health Canada Web page (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index_e.html) and on Lundbeck Canada's Web site (www.lundbeck.ca).

Health care professionals should inform patients and their caregivers about the signs of these rare but serious skin reactions and that Ebixa should be discontinued at the first appearance of skin rash.

Cases of skin reactions or other serious or unexpected adverse reactions in patients receiving Ebixa® should be reported to Lundbeck or Health Canada.

Medical Information and Pharmacovigilance

- Lundbeck Canada Inc.
  1000 La Gauchetiere W., Suite 0500
  Montreal, QC H3B 4W5
- Or call toll-free at 1-866-880-4636; or
- By email: CanadaMedicalInformation@Lundbeck.com

You can report any suspected adverse reactions associated with the use of health products to Health Canada:

- Call toll-free at 1-866-234-2345; or
- Visit 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

Lundbeck Canada continues to ensure that up-to-date information concerning the use of Ebixa® is available to Canadian Healthcare Professionals.

Sincerely,

Nina Courchesne, B.Pharm, M.Sc
Senior Manager,
Medical Information and Pharmacovigilance