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Lundbeck Canada Inc.

May 5th, 2010

Attention: Health Care Professionals

Re: Updated Product Monograph of Ebixa®

Dear Sir, Madam,

This letter, initiated voluntarily by Lundbeck, is to inform you of the recent approval by Health Canada of the updated Product Monograph for Ebixa® † (memantine).

This revised Product Monograph includes updated information under the following sections:

Clinical trials (editorial changes)
Precautions – Special populations - Renal impairment
Dosage and administration – Special populations - Renal impairment
Part III: Consumer information

The main change pertains to the dosage recommendation in the renally impaired population:

Information found in <u>previous</u> Product Monograph:
Renal impairment: In patients with normal to mildly impaired renal function (creatinine clearance >60 ml/min/1.73 m²) no dose reduction is needed. In patients with moderate renal impairment (creatinine clearance 40 60 ml/min/1.73 m²) daily dose should be reduced to 10 mg per day. In patients with severe renal impairment the use of Ebixa® has not been systematically evaluated and is therefore not recommended in these patients.

Information found in <u>current</u> updated Product Monograph (dated March 22, 2010):
Renal impairment: In patients with mildly impaired renal function (creatinine clearance 50 - 80 ml/min) no dosage adjustment is required. In patients with moderate renal impairment (creatinine clearance 30 - 49 ml/min) the daily dose should be 10 mg per day. If well tolerated after at least 7 days of treatment, and based on clinical response, the dose may be increased up to 20 mg/day according to the standard titration scheme. In patients with severe renal impairment (creatinine clearance 15 - 29 ml/min) the daily dosage should be 10 mg per day.

Please refer to the full updated Product Monograph that is now accessible from the Health Canada Website (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index_e.html) and on Lundbeck Canada's Website (www.lundbeck.ca).

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

Please do not hesitate to share this information with your colleagues.
Should you have any questions, please contact our **Medical Information Service** at 1-866-880-4636.

Sincerely,

Nina Courchesne, B.Pharm, M.Sc
Manager, Medical Information and Pharmacovigilance
Lundbeck Canada Inc.

† Ebixa®, a N-mehtyl-D-aspartate receptor antagonist indicated for the symptomatic treatment of patients with moderate to severe dementia of the Alzheimer's type, has been issued marketing authorization with conditions, to reflect the promising nature of the clinical evidence and the need for a confirmatory study to verify the clinical benefit.