Lundbeck Canada Inc.

December 20th, 2011

Attention: Health Care Professional

Re: Updated Product Monographs of Fluanxol®, Fluanxol® Depot, Clopixol®, Clopixol®-Acuphase and Clopixol® Depot

Dear Madam,

Dear Sir,

This letter, initiated voluntarily by Lundbeck, is to inform you of the recent approval by Health Canada of the updated Product Monographs for Fluanxol® (flupentixol dihydrochloride) and Fluanxol® Depot (flupentixol decanoate) and for Clopixol® (zuclopenthixol hydrochloride), Clopixol®-Acuphase (zuclopenthixol acetate) and Clopixol® Depot (zuclopenthixol decanoate). Fluanxol® and Clopixol® are antipsychotic agents marketed by Lundbeck in Canada.

These revised Product Monographs include updated information under the following sections:

WARNINGS AND PRECAUTIONS

Endocrine and Metabolism

Hyperprolactinemia: Long-standing hyperprolactinemia, when associated with hypogonadism, may lead to decreased bone mineral density in both female and male subjects.

Hyperglycemia: Diabetic ketoacidosis (DKA) has occurred in patients with no reported history of hyperglycemia. Patients should have baseline and periodic monitoring of blood glucose and body weight.

Genitourinary: Rare cases of priapism have been reported with antipsychotic use, such as flupentixol and zuclopenthixol. This adverse reaction, as with other psychotropic drugs, did not appear to be dose-dependent and did not correlate with the duration of treatment.

Hematologic

Neutropenia, granulocytopenia and agranulocytosis have been reported during antipsychotic use. Therefore, it is recommended that patients have their complete blood count (CBC) tested prior to starting flupentixol and zuclopenthixol and then periodically throughout the treatment.

Special Populations

Pregnant and Nursing Women:

Non-Teratogenic Effects

Neonates exposed to antipsychotic drugs (including flupentixol and zuclopenthixol) during the third trimester of pregnancy are at a risk for extrapyramidal and/or withdrawal symptoms following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence,
respiratory distress and feeding disorder in these neonates. These complications have varied in severity; while in some cases symptoms have been self-limited, in other cases neonates have required intensive care unit support and prolonged hospitalization.

ADVERSE REACTIONS

Miscellaneous
Patients should be advised of the risk of severe constipation during flupentixol and zuclopenthixol treatment, and that they should tell their doctor if constipation occurs or worsens, as they may need laxatives.

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 Fluanxol® and Clopixol® 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.