



Lundbeck Canada Inc.

October 24th, 2011

Attention: Health Care Professionals

Re: Updated Product Monograph of Fluanxol[®] and Fluanxol[®] 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 Monograph for Fluanxol[®] (flupentixol dihydrochloride), and Fluanxol[®] Depot (flupentixol decanoate). Fluanxol[®] is an antipsychotic agent marketed by Lundbeck in Canada.

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

Change in the spelling of the generic name from “flupent~~h~~ixol” to “flupentixol” in order to follow the current nomenclature of reputable sources, such as the British Pharmacopoeia and Martindale.

WARNINGS AND PRECAUTIONS

Elderly Patients with Dementia

Analyses of thirteen placebo-controlled trials with various atypical antipsychotics (modal duration of 10 weeks) in elderly patients with dementia showed a mean 1.6 fold increase in the death rate in the drug-treated patients. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. Flupentixol is not indicated for the treatment of patients with dementia (see PRECAUTIONS, Use in Elderly, Use in Geriatric Patients with Dementia).

Cardiovascular (New Class warning for all antipsychotics)

Venous Thromboembolism: Cases of venous thromboembolism (VTE) have been reported with antipsychotic drugs. All possible risk factors for VTE should be identified before and during treatment with flupentixol and preventive measures undertaken.

Special Populations (New Class warning for older antipsychotics)

Cerebrovascular Adverse Events (CVAEs) including stroke in Elderly Patients with Dementia: An increased risk of cerebrovascular adverse events has been seen in the dementia population in clinical trials with some atypical antipsychotics. The mechanism for this increased risk is not known. There is insufficient data to know if there is an increased risk of cerebrovascular events associated with flupentixol. An increased risk however cannot be excluded. Flupentixol is not indicated in elderly patients with dementia.

Mortality in Geriatric Patients with Dementia-related Psychosis: In elderly patients with dementia-related psychosis, the efficacy and safety of flupentixol has not been studied. Observational studies suggest that elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Flupentixol is not indicated for the treatment of patients with dementia-related psychosis.

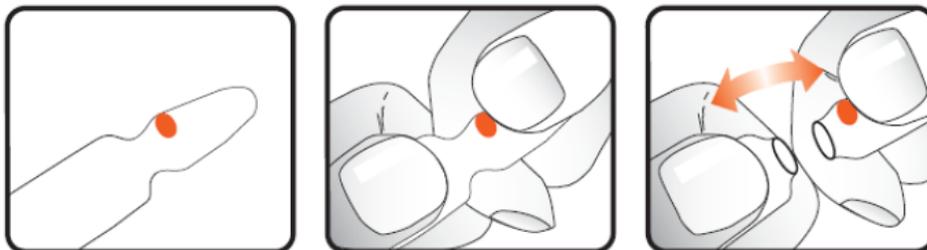
Vascular disease: Flupentixol should be used with caution in patients with risk factors for stroke or with a history of stroke.

DOSAGE AND ADMINISTRATION

Administration

Fluanxol[®] Depot (flupentixol decanoate)

How to open an ampoule:



The ampoule can only be broken in one direction. The breaking point can be found on the neck of the ampoule next to the red dot. The pressure must be applied under the red dot.

Hold the ampoule with the red dot facing up. Position your thumbs on each side of the neck of the ampoule, one on the top of the red dot and the other on the label. Apply pressure using your index fingers and snap the ampoule in an upward direction. Keep the ampoule away from you at all times when opening.

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[®] 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.