January 15th, 2013

Attention: Health Care Professionals

Re: Updated Product Monograph of Cipralex® to include the new Cipralex MELTZ® orodispersible tablet

Dear Sir, Madam,

This letter, initiated voluntarily by Lundbeck Canada, is to inform you of the approval by Health Canada of the updated Product Monograph for Cipralex® (escitalopram oxalate) (August 13, 2012) which now includes information related to Cipralex MELTZ® orodispersible tablet (escitalopram base). Cipralex MELTZ® has been available in Canada since January 2013. Cipralex (Cipralex® and Cipralex MELTZ®) is an antidepressant / anxiolytic / antiobsessional marketed by Lundbeck in Canada.

The updated Product Monograph includes information related to Cipralex MELTZ® under the following sections:

Important Information to note all through the Product Monograph
In this document, unless otherwise specified, “Cipralex” refers to both Cipralex® (escitalopram oxalate) and Cipralex MELTZ® (escitalopram base).

Adverse reactions / Comparative study
In a study comparing Cipralex MELTZ® orodispersible tablets (escitalopram base) to Cipralex® film-coated tablet (escitalopram oxalate), the adverse event profile was consistent with that observed in controlled clinical trials, with the exception of “feeling cold” (2/30) which occurred in a group of subjects administered the Cipralex MELTZ® orodispersible 20 mg tablet.

Dosage and Administration / Dosing consideration
Cipralex MELTZ® (escitalopram base) orodispersible tablets: The orodispersible tablet should be placed on the tongue, where it rapidly disintegrates and can be swallowed without water. The orodispersible tablet is fragile and should be handled carefully. The Cipralex MELTZ® (escitalopram base) orodispersible tablet can be used as an alternative to the Cipralex® (escitalopram oxalate) tablet.

Since Cipralex MELTZ® tablets are only available as 10 and 20 mg, they cannot be used when 5 mg or 15 mg doses are required.

Action and Clinical Pharmacology / Comparison of Cipralex® (escitalopram oxalate) tablets with Cipralex MELTZ® (escitalopram base) orodispersible tablets
The performance of Cipralex MELTZ® 10 and 20 mg and Cipralex® tablets can be considered equivalent with respect to the delivery of escitalopram.

Storage and stability
Cipralex MELTZ® (escitalopram base) orodispersible tablets should be stored in a dry place in the original package in order to protect from light. Store between 15 and 30°C. Excursions above 30°C should be avoided.
Dosage forms, composition and packaging

Cipralex MELTZ®: escitalopram orodispersible tablets contain escitalopram base corresponding to 10 mg or 20 mg escitalopram, and the following non medicinal ingredients: basic butylated methacrylate copolymer, citric acid anhydrous, crospovidone, hypromellose, magnesium stearate, mannitol, microcrystalline cellulose, mint flavour (natural and artificial), sodium hydrogen carbonate, sucralose (E955).

Availability of dosage forms

Cipralex MELTZ® (escitalopram base) Orodispersible Tablets
10 mg orodispersible tablets: Each white to off white, slightly speckled, flat-faced, round, beveled edge tablet debossed with ELO on one side contains: escitalopram 10 mg (as escitalopram base). Aluminium blister strips in cartons of 30 or 60 orodispersible tablets per carton.
20 mg orodispersible tablets: Each white to off white, slightly speckled, flat-faced, round, beveled edge tablet debossed with ENO on one side contains: escitalopram 20 mg (as escitalopram base). Aluminium blister strips in cartons of 30 or 60 orodispersible tablets per carton.

Clinical trials / Comparative study

Cipralex® (escitalopram oxalate) tablets, 2 x 10 mg, were compared to Cipralex MELTZ® (escitalopram base) orodispersible tablets 2 x 10 mg and 1 x 20 mg in an open-label, randomised, crossover, study in 32 healthy young men. Each subject received one dose of each of the three treatments, according to one of six randomly allocated treatment sequences. Each dose was separated by a washout period of 14 to 28 days.

The performance of Cipralex MELTZ® 10 and 20 mg and Cipralex® tablets can be considered equivalent with respect to the delivery of escitalopram.

Consumer Information

The consumer Information section of the Product Monograph has also been updated to include information related to Cipralex MELTZ®.

Please refer to the full updated Product Monograph that is available on Lundbeck Canada’s Website (http://www.lundbeck.com/ca).

Lundbeck Canada will continue to ensure that the most up-to-date information concerning the use of Cipralex® and Cipralex MELTZ® 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
Senior Manager, Medical Information and Pharmacovigilance
Lundbeck Canada Inc.