



Lundbeck Canada Inc.

January 15th, 2013

Attention: Health Care Professionals

Re: Updated Product Monograph of Cipralext[®] to include the new Cipralext 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 Cipralext[®] (escitalopram oxalate) (August 13, 2012) which now includes information related to Cipralext MELTZ[®] orodispersible tablet (escitalopram base). Cipralext MELTZ[®] has been available in Canada since January 2013. Cipralext (Cipralext[®] and Cipralext MELTZ[®]) is an antidepressant / anxiolytic / antiobsessional marketed by Lundbeck in Canada.

The updated Product Monograph includes information related to Cipralext MELTZ[®] under the following sections:

Important Information to note all through the Product Monograph

In this document, unless otherwise specified, “Cipralext” refers to both Cipralext[®] (escitalopram oxalate) and Cipralext MELTZ[®] (escitalopram base).

Adverse reactions / Comparative study

In a study comparing Cipralext MELTZ[®] orodispersible tablets (escitalopram base) to Cipralext[®] 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 Cipralext MELTZ[®] orodispersible 20 mg tablet..

Dosage and Administration / Dosing consideration

Cipralext 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 Cipralext MELTZ[®] (escitalopram base) orodispersible tablet can be used as an alternative to the Cipralext[®] (escitalopram oxalate) tablet.

Since Cipralext 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 Cipralext[®] (escitalopram oxalate) tablets with Cipralext MELTZ[®] (escitalopram base) orodispersible tablets

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

Storage and stability

Cipralext 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

Cipralext[®] 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

Cipralext[®] 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

Cipralext[®] (escitalopram oxalate) tablets, 2 x 10 mg, were compared to Cipralext[®] 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 Cipralext[®] MELTZ[®] 10 and 20 mg and Cipralext[®] 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 Cipralext[®] 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 Cipralext[®] and Cipralext[®] 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.