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Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

Common Drug Review *

Submission Status

Product: Ebixa

Generic Name: memantine hydrochloride

Manufacturer: Lundbeck Canada Inc.

Submission Type: NEW

Date Submission Received: 2004-Dec-21 **Date NOC Issued:** 2004-Dec-08

Targeted CEDAC Meeting: 2005-Sep-21 **Priority Review Granted:** Denied

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Initial Submission Deemed Complete	5	2005-Jan-05	2005-Jan-05	Submission initially deemed complete on January 5, 2005. Reviewed at April 20, 2005 CEDAC meeting and deferred pending receipt of additional information. Additional information requested and received June 1, 2005. Additional information requires detailed review.
	Submission Deemed Complete	5	2005-Jun-01	2005-Jun-01	
2	CDR Reviewers' Reports Completed • Reviewers selected and contracted • Literature search and selection completed • Systematic review of clinical data completed • Critical appraisal of pharmacoeconomic (PE) data completed • Clinical and PE reports written • Reports edited and finalized • Reviewers' reports sent to manufacturer	45	2005-Aug-05	2005-Jul-13	
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2005-Aug-16	2005-Jul-29	Due date for Manufacturer's comments is July 22, 2005 Request for extension received July 21, 2005. Extension granted, due date for manufacturer's comments July 29, 2005. Manufacturer comments received July 29, 2005.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2005-Aug-25	2005-Aug-10	Due date for reviewer's reply August 10, 2005.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2005-Sep-07	2005-Sep-07	
6	CEDAC Meeting		2005-Sep-21	2005-Sep-21	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2005-Sep-28	2005-Sep-28	
8	Embargo Period*** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation and Reasons for Recommendation	10	2005-Oct-13	2005-Oct-13	Request for reconsideration received October 13, 2005.
9 (a)	Final Recommendation sent to Drug Plans, ACP, and Manufacturer (No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved)	5		2005-Nov-23	
	OR				
9 (b)	Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
	OR				
9 (c)	Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates	2005-Nov-16	2005-Nov-16	
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2005-Nov-23	2005-Nov-23	

* Refer to the Procedure for Common Drug Review on the Common Drug Review section of www.ccohta.ca for more details.

** The CDR review process is initiated AFTER a submission is deemed complete. The target dates for this report are based on the CEDAC meeting schedule, which is posted on www.ccohta.ca.

*** The Recommendation and Reasons for Recommendation are to be held in confidence and not acted upon until after the CDR Directorate has issued the notice of Final Recommendation.