## 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

### 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.


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***  

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) | | | |

### 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

---

** 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.