



## Common Drug Review \*

### Submission Status

**Product:** Relistor  
**Generic Name:** methylnaltrexone bromide  
**Manufacturer:** Wyeth Canada  
**Submission Type:** New  
**Date Submission Received:** 2008-May-07      **Date NOC Issued:** 2008-Mar-28  
**Targeted CEDAC Meeting:** 2008-Oct-15      **Priority Review Granted:** Not Requested

Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments	
1	Submission Assessment	5	2008-May-14	2008-May-14	Category 1 Submission requirements deemed incomplete May 14, 2008.
	Submission deemed complete			2008-May-20	Submission deemed complete.
2	CDR Reviewers' Reports Completed <ul style="list-style-type: none"> <li>• Reviewers selected and contracted</li> <li>• Literature search and selection completed</li> <li>• Systematic review of clinical data completed</li> <li>• Critical appraisal of pharmacoeconomic (PE) data completed</li> <li>• Clinical and PE reports written</li> <li>• Reports edited and finalized</li> <li>• Reviewers' reports sent to manufacturer</li> </ul>	45	2008-Aug-05	2008-Aug-05	Additional information requested June 3, 2008. Response to request for additional information received June 4, 2008. Additional information requested June 9, 2008. Additional information requested June 12, 2008. Additional information received June 16, 2008. Additional information received June 18, 2008. Additional information requested June 19, 2008. Additional information requested July 4, 2008. Additional information received July 7, 2008. Additional information received July 22, 2008. Additional information received July 25, 2008.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2008-Aug-14	2008-Aug-14	
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2008-Aug-25	2008-Aug-25	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2008-Sep-30	2008-Sep-30	
6	CEDAC Meeting		2008-Oct-15	2008-Oct-15	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2008-Oct-22	2008-Oct-22	
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	2008-Nov-05	2008-Dec-03	Request for extension of Embargo Period received November 3, 2008. Extension approved, new end date for Embargo Period is December 3, 2008.  Request for Reconsideration received December 3, 2008.
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			
<b>OR</b>					
9 (b)	Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
<b>OR</b>					
9 (c)	Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates	2009-Jan-21	2009-Jan-21	
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2009-Jan-28	2009-Jan-28	Notice of Final Recommendation issued.

\* Refer to the Procedure for Common Drug Review on the Common Drug Review section of [www.cadth.ca](http://www.cadth.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.cadth.ca](http://www.cadth.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.

Reflects updates as of Thursday noon.