Common Drug Review *

Submission Status

Product: NuvaRing

Generic Name: etonogestrel/ethinyl estradiol

Manufacturer: Organon Canada Ltd.

Submission Type: New

Date Submission Received: 2006-May-05 **Date NOC Issued:** 2004-May-11

Targeted CEDAC Meeting: 2006-Sep-20 **Priority Review Granted:** Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2006-May-12	2006-May-26	Submission incomplete - missing information requested May 24, 2006. Requested information received May 25, 2006. Submission deemed complete.
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	2006-Jul-31	2006-Aug-01	Additional information requested June 7, 2006. Additional information received June 8, 2006. Additional information requested July 6, 2006. Additional information received July 7, 2006.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-Aug-10	2006-Sep-01	Request for extension received August 3, 2006. Extension granted, new due date for manufacturer's comments is September 1, 2006. New target CEDAC date October 18, 2006.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-Sep-13	2006-Sep-13	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2006-Oct-03	2006-Oct-03	Additional information requested September 27, 2006. Additional information received September 29, 2006.
6	CEDAC Meeting		2006-Oct-18	2006-Oct-18	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2006-Oct-25	2006-Oct-25	
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	2006-Nov-08	2006-Nov-08	Request for clarification received October 30, 2006.
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			
	OR				
9 (b)	Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5	2006-Nov-29	2006-Nov-29	Placed on the November 22, 2006 CEDAC agenda in response to the ACP request for clarification. Notice of Final Recommendation issued.
	OR				
9 (c)	Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates			
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5			

* Refer to the Procedure for Common Drug Review on the Common Drug Review section of 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.
*** 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.