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Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

Common Drug Review *

Submission Status

Product: Gynazole.1

Generic Name: butoconazole nitrate, 2% vaginal cream

Manufacturer: Ferring Inc.

Submission Type: NEW

Date Submission Received: 30/6/2004 **Date NOC Issued:** 23/12/2003

Targeted CEDAC Meeting: 2004-Nov-17 **Priority Review Granted:** Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2004-Jul-08	2004-Jul-26	Submission Incomplete - Missing information requested July 9/04. Missing information provided July 22, 2004. Submission deemed complete July 26, 2004.
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	2004-Oct-04	2004-Oct-06	Additional information requested August 24, 2004. Additional information received August 31, 2004.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2004-Oct-14	2004-Oct-18	Due date for manufacturer's comments October 18, 2004.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2004-Oct-25	2004-Oct-25	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2004-Nov-01	2004-Nov-04	
6	CEDAC Meeting		2004-Nov-17	2004-Nov-17	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, CDRC and Manufacturer	5	2004-Nov-24	2004-Nov-24	
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	2004-Dec-08	2004-Dec-08	Request for reconsideration received December 8, 2004.
9 (a)	Final Recommendation sent to Drug Plans, CDRC, 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, CDRC, 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-Jan-19	2005-Jan-19	
10	Final Recommendation sent to Drug Plans, CDRC, and Manufacturer	5	2005-Jan-26	2005-Jan-26	Notice of Final Recommendation Issued.

* 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.