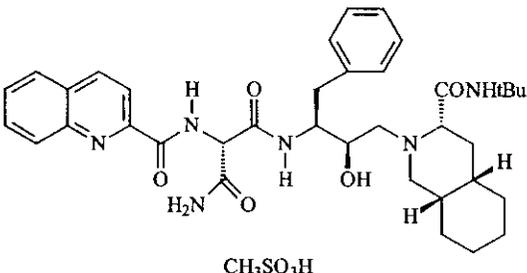


CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-628/S-016

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW		1. ORGANIZATION HFD-530		2. NDA NUMBER 20-628	
3. NAME AND ADDRESS OF APPLICANT (City and State) Hoffman-La Roche Inc. 340 Kingsland Street Nutley, NJ 07110 Attn: Barbara S. Taylor, Ph.D.				4. TYPE/DUE DATE CBE-0 10/30/01	
				5. SUPPLEMENT(S)	
				NUMBER(S)	DATE
SLR-016		4/27/01	4/30/01		
6. NAME OF DRUG INVIRASE® Capsules			7. NONPROPRIETARY NAME saquinavir mesylate capsules		
8. SUPPLEMENT(S) PROVIDES FOR: Addition of warnings to the package inserts and container labels.				9. AMENDMENTS / REPORTS	
10. PHARMACOLOGICAL CATEGORY Anti-HIV		11. HOW DISPENSED <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(S)	
13. DOSAGE FORM(S) Hard gelatin capsules			14. POTENCY(IES) 200 mg		
15. CHEMICAL NAME AND STRUCTURE [3S-[2[1R*(R*),2S*],3α,4aβ,8aβ]]-N ¹ [3-[[[(1,1-dimethylethyl)amino]carbonyl]octahydro-2-(1H)-isoquinolinyl]-2-hydroxy-1-(phenylmethyl)propyl]-2-[(2-quinolinylcarbonyl)-amino]butanediamide monomethanesulfonate salt				16. MEMORANDA	
 <p style="text-align: center;">CH₃SO₃H</p>					
17. COMMENTS					
18. CONCLUSIONS AND RECOMMENDATIONS This Supplement provides for changes in the labeling of Invirase (saquinavir mesylate) capsules. The changes concern drugs that should not be taken with Invirase. There are no new CMC data and the How Supplied section of the insert is not changed. A warning has been added to the bottle label but the content and prominence of the existing texts has not been changed. There are no cartons used with this product. This Supplement is therefore recommended for approval from a CMC perspective.					
19. REVIEWER					
NAME George Lunn, Ph.D.		SIGNATURE [signed electronically in DFS]		DATE COMPLETED	
20. CONCURRENCE: HFD-530/SMiller [signed electronically in DFS]					
DISTRIBUTION	<input checked="" type="checkbox"/>	Original Jacket	<input checked="" type="checkbox"/>	GLunn	<input checked="" type="checkbox"/> MHolloman
	<input checked="" type="checkbox"/>	Division File	<input checked="" type="checkbox"/>	SMiller	<input checked="" type="checkbox"/> LLewis
	<input checked="" type="checkbox"/>	HFD-830/CChen			

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

George Lunn
5/11/01 11:26:48 AM
CHEMIST

Bottle labels with Alert for Invirase

Stephen Paul Miller
5/11/01 04:24:01 PM
CHEMIST

*Appears This Way
On Original*