

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19386

APPROVAL LETTER



Food and Drug Administration
Rockville MD 20857

NDA 19-386

JAN 19 2000

Baxter Pharmaceutical Products Inc.
Attention: Ms. Priya Jambhekar
95 Spring Street
New Providence, NJ 07974

Dear Ms. Jambhekar:

We acknowledge receipt on November 8, 1999 of your November 3, 1999 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Brevibloc (esmolol hydrochloride) 250 mg/mL Ampule and 10 mg/mL Vial for Injection.

This supplemental new drug application provides for reposition of the "Must Be Diluted" warning flag on Brevibloc ampules in order to increase its prominence substantially.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (immediate container and carton labels submitted November 3, 1999). Accordingly, the application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call:

Ms. Zelda McDonald
Regulatory Project Manager
(301) 594-5300.

Sincerely yours,

RS/ 1/19/00

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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FINAL PRINTED LABELING

Labeling: original
NDA No. 19-386 - 1-12-00
Reviewed by: J. McDonald 1/18/00

NDA 19-386:
BREVIBLOC (esmolol HCl) Inj.
Revised 10 mL Ampul Label with "Must be Diluted" Warning Flag
Code 300-185-01

APPROVED

JAN 19 2000

NDC 10019-025-18

Brevibloc® Injection
(esmolol hydrochloride) **Rx only**

2500 mg/10 mL
(250 mg/mL)

10 mL Ampul

NOT FOR DIRECT
I.V. INJECTION
MUST BE DILUTED
BEFORE USE

FOR INTRAVENOUS USE

Each mL contains: 250 mg esmolol HCl in 25% Propylene Glycol, USP; 25% Alcohol, USP; and Water for Injection, USP. Buffered with Sodium Acetate, USP and Glacial Acetic Acid, USP. Sodium Hydroxide and/or Hydrochloric Acid added to adjust pH. See package insert for complete information on dilution, dosage and administration. For Product Inquiry 1 800 ANA DRUG

Baxter
Mfg. for an affiliate of Baxter Healthcare Corporation
Deerfield, IL 60015 USA
by Fausdin Puerto Rico, Inc.
Aguadilla, PR 00604 USA 300-185-01



N 3 10019 02518 6

MUST BE DILUTED
MUST BE DILUTED
Remove top portion of label at perforation before opening.
MUST BE DILUTED - MUST BE DILUTED

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CHEMISTRY REVIEW(S)

DEC 6 1999

CHEMIST'S REVIEW		1. ORGANIZATION HFD-110	2. NDA Number 19-386
3. Name and Address of Applicant (City & State) Baxter Pharmaceutical Products Inc. 95 Spring Street New Providence, NJ 07974		4. Supplement(s) Number(s) Date(s) SNC SLR-016 11/3/99	
5. Drug Name Brevibloc	6. Nonproprietary Name Esmolol HCl	7. Amendments & Other (reports, etc) Dates	
8. Supplement Provides For: proposal for Revision in Format of Ampul Label - specifically: Positioning of "Must Be Diluted" Warning Flag.			
9. Pharmacological Category Anti-adrenergic (β receptor)	10. How Dispensed <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC	11. Related IND(s)/ NDA(s)/DMF(s)	
12. Dosage Form(s) Intravenous injection	13. Potency(ies) 250mg/mL 10mL amp 10 mg/mL 10mL vial		
14. Chemical Name and Structure methyl p-[2-hydroxy-(isopropylamino)propoxy] hydrocinnamate hydrochloride		15. Records/Reports Current <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Reviewed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
16. Comments On August 5, 1999 in teleconference Ms. McDonald advised Baxter PPI to submit the revised label concept for Agency review. Accordingly find enclosed: <ul style="list-style-type: none"> • rationale for the proposed revision, including the revised description of the proposed revision (Tab A); • comparison of the current and proposed ampul labels (Tab B); • samples of the current and proposed ampul labels (Tab C); • dummy samples of Brevibloc ampuls labeled the proposed labels. <p>Baxter PPI would like to submit the revised labels in a Changes Being Effected Supplement and implement the revised labels immediately upon the Agency's receipt of the supplement.</p>			
17. Conclusions and Recommendations Satisfactory as far as chemistry is concerned.			
18. REVIEWER			
Name Danute G. Cunningham	Signature <i>/S/</i>	Date Completed November 12, 1999	
Distribution: <input checked="" type="checkbox"/> Original Jacket <input type="checkbox"/> Reviewer <input type="checkbox"/> Division File <input type="checkbox"/> CSO			

19386SNC.SUP

/S/
12-6-99