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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-283/S-002

Medical Review(s)



DIVISION OF CARDIO-RENAL DRUG PRODUCTS
Clinical Review

NDA: 21-283

Sponsor: Novartis

Submission: SLR-002 (18 October 2001): a request to increase the starting dose from 80 to 160 mg for valsartan in the treatment of mild-to-moderate essential hypertension.

Review date: February 8, 2002

Reviewers: N. Stockbridge, M.D., Ph.D., HFD-110

Distribution: NDA 21-283

HFD-110/Project Manager

The sponsor proposes to make the usual starting dose in essential hypertension be 160 mg, rather than 80 mg, as currently labeled. The rationale offered is (1) greater blood pressure reduction has public health benefits, (2) achieving the target reduction in fewer visits is desirable, and (3) 160 mg is safe as a starting dose.

The sponsor has provided a summary of fixed-dose dose-response from a number of placebo-controlled studies. These data are shown in Figure 1.

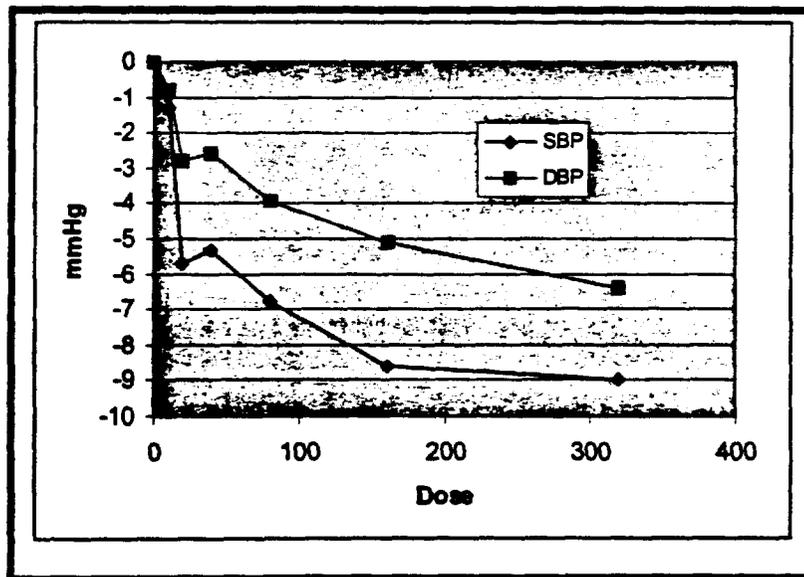


Figure 1. Raw mean dose-response for valsartan

Data from 9 randomized, double-blind, parallel, placebo-controlled studies of valsartan as reported by Pool et al. (1998) *Clinical Therapeutics* 20(6):1106-1114.

SLR-002
Change in starting dose

NDA 21-283
Valsartan for hypertension

320 mg or a diuretic may be added. Addition of a diuretic has a greater effect than dose increases beyond 80 mg.

This supplement should be approved.

**APPEARS THIS WAY
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Norman Stockbridge
2/8/02 11:36:15 AM
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