CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
74787

DRAFT FINAL PRINTED LABELING
of carcinogenesis. Studies with laboratory, using dermal lethal assays in rats and mice, and exposing mice to microorganisms according to modified Ames tests, showed no evidence of mutagenicity.

**Precautionary Category**

Teratogenic studies have been performed in laboratory rats and rabbits at oral doses up to approximately 4 times the maximum recommended human dose (MRHD) respectively. No teratogenic effects were observed in laboratory rats at oral doses of up to 7 times the MRHD. In rabbits given 1.7 times the MRHD there was no evidence of drug-related harm to the fetus. There are no adequate and well-controlled studies in pregnant women. Laboratory should be used during pregnancy only if the potential benefit justifies the possible risk to the fetus.

**Hemorrhagic Effects**

Hypertension, bradycardia, hypotension, and respiratory depression have been reported in infants of mothers who were treated with labetalol for hypertension during pregnancy. Oral administration of labetalol to rats during late gestation through weaning at doses of 2 to 4 times the MRHD resulted in a decrease in maternal survival.

Labetalol is excreted in human milk. Caution should be exercised when labetalol is administered to a nursing woman.
LABETALOL HYDROCHLORIDE TABLETS, USP
300 mg

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300 mg

LABETALOL HYDROCHLORIDE TABLETS, USP
300 mg
LABETALOL HYDROCHLORIDE TABLETS, USP

200 mg