Labetalol HCl Injection, USP is a clear, colorless to light yellow, aqueous, sterile, isotonic solution for intravenous injection. It has a pH range of 3 to 4. Each milliliter contains 5 mg of labetalol HCl, 45 mg of anhydrous dextrose, 0.1 mg of edetate disodium, 0.8 mg of methylparaben and 0.1 mg of propylparaben as preservatives; and citric acid monohydrate and sodium hydroxide, as necessary, to bring the solution into the pH range.

**CLINICAL PHARMACOLOGY**

Labetalol combines both selectivity, competitive, alpha-1 blocker-blocking and nonselective, competitive, beta-adrenergic blocking activity in a single agent. In man, the alpha-1-receptor blocking activity of labetalol has been estimated to be approximately 1:3 and 1:7 following oral and intravenous administration, respectively. Beta, agonist activity has been demonstrated with labetalol in both normal and ischemic hearts in vitro. In animals, at doses greater than those required for alpha- or beta-blockade activity, a membrane stabilizing effect has been demonstrated.

Pharmacokinetics: Labetalol HCl is rapidly absorbed after oral administration. The peak plasma concentration appears approximately 1 to 2 hours after ingestion. The plasma half-life of labetalol is about 1 hour following intravenous administration of single doses and about 2 hours following oral administration. The plasma clearance is about 3 liters per minute per square meter of body surface area. The metabolism of labetalol is mainly through conjugation to glucuronide.
being treated with labetalol have a positive urine test for amphetamine usu-
ally reported with labetalol HCl with the incidence per 100 patients. Sweating was noted in 4 of 100 patients, and flushing occurred in 1 of 100 patients. The following also were reported with labetalol: urticaria, pruritus, angioedema, dyspnea, pruritus, angioedema, dyspnea, and anaphylactoid reactions. These species is 50 to 60 mg/kg. The oculomucocutaneous syndrome associated with the beta-blocker response is similar to that observed in other species. In humans, adverse events have been more reactive to repeated challenge, either accidental, diagnostic, or therapeutic. Labetalol has been reported to produce a false-positive test for the urine may result in falsely elevated levels of urinary catecholamines, epinephrine when used to treat allergic reaction. Risk of Anaphylactic Reaction: anesthesiologist should be informed when a patient is receiving labetalol. The contents of either two 20 mL vials (40 mL), or 40 mL multidose vials, individually-boxed (NDC 55390-130-20) and 40 mL (200 mL) multidose vials, individually-boxed (NDC 55390-130-86). Store between 2° to 30°C (36° to 86°F). Do not freeze. Labetalol HCI injection was tested for compatibility with commonly used intravenous fluids at final concentrations of 1.25 mg to 3.75 mg of labet-
alol HCl per milliliter of the mixture. Labetalol HCI injection was found to be compatible with and stable (for 24 hours refrigerated or at room temperature) in mixtures with the following solutions: ringer’s injection: labetalol ringer’s injection: 10% dextrose and ringer’s injection: 5% lactated ringer’s injection: 5% dextrose and sodium chloride injection: and 5% dextrose and 0.33% sodium chloride injection. Labetalol HCI injection was NOT compatible with 5% sodium bicarbon-
ate injection. Care should be taken when administering alkaline drugs, including furosemide, in combination with labetalol. Compatibility should be assured prior to administering these drugs together. Synergism has been shown between halothane anesthesia and intrave-
ous infusion of labetalol. The dilution should be administered at a rate of 2 mL/min to de-
iever finds pharmacologic evidence that norepinephrine may be the drug of choice.

Cardiovascular System: Venricular arrhythmia in 1.

ADVERSE REACTIONS

Labetalol HCl injection should be obtained. Most adverse effects have been mild and transient, and, in controlled trials involving 90 patients, did not require labetalol withdrawal. Symptomatic postural hypotension (in-
cidence, 50%) is likely to occur if these patients are tilted or allowed to assume the upright position within 3 hours of receiving labetalol. Moder-
ate hypotension occurred in 1 of 100 patients while supine. Increased sweating was noted in 4 of 100 patients, and flushing occurred in 1 of 100 patients. The following also were reported with labetalol HCl injection nov 19 19 16

Fatigue 2 1 4 4 5 3 6 7 10 6

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