The effect of hepatic impairment on the pharmacokinetics of Levalbuterol HCl Inhalation Solution has not been evaluated and for comparison, adult data obtained by conventional pharmacokinetic analysis from a different study also are presented.

Information available in the published literature suggests that the primary enzymes responsible for the metabolism of albuterol enantiomers in humans are CYP2D6 and CYP3A4. When subjects were administered either intravenously or via inhalation either 0.063 mg of Levalbuterol HCl Inhalation Solution or 0.125 mg of Levalbuterol HCl Inhalation Solution, systemic beta-adrenergic adverse effects were observed with all active doses and were generally dose-related for (R)-albuterol. These data support lower doses for children 6-11 years old compared with the adult doses (see Pharmacology).

Levalbuterol relaxes the bronchial smooth muscle in asthmatic patients and is considered to be beneficial in the treatment of mild-to-moderate asthma. Levalbuterol HCl Inhalation Solution should be discontinued if the patient develops cardiac arrhythmias. The occurrence of cardiac arrhythmias should suggest the possibility of other underlying etiologies and cause a thorough search for such possible etiologies. Patients receiving Levalbuterol HCl Inhalation Solution should be monitored for the development of cardiac arrhythmias and the occurrence of any other adverse effects.

To determine the relationship between serum concentrations and bronchodilator effect, 12 adult volunteers received an inhalation dose of 0.3 mg of racemic albuterol sulfate. The drug induced a mean bronchodilator effect of 15% and a peak concentration of 150 ng/mL was observed. These results suggest that the bronchodilatory effects of racemic albuterol are attributed to the (R)-enantiomer.

In a randomized, double-blind, placebo-controlled cross-over study, 142 adult patients with mild-to-moderate asthma were treated with either 0.25, 0.5, or 1.25 mg of racemic albuterol sulfate. Levalbuterol HCl Inhalation Solution was found to be significantly more effective than placebo and was comparable in efficacy to an equal dose of racemic albuterol sulfate. Levalbuterol HCl Inhalation Solution is contraindicated in patients with a history of hypersensitivity to levalbuterol HCl or racemic albuterol.
Drug Interactions
Other drugs with a serious potential for respiratory depression or with which the administration of Levalbuterol HCI Inhalation Solution would be contraindicated because of the risk of serious interactions are being studied. (See WARNINGS.)

The safety and efficacy of Levalbuterol HCI Inhalation Solution in patients with obstructive airway disease who are receiving levalbuterol HCI and diuretics on a chronic basis is unclear.

In a study in which 10 patients were treated with beta-blockers. However, under certain circumstances, e.g., prophylaxis after myocardial infarction, there may be no acceptable alternative to the use of beta-blockers. Under these circumstances, beta-blockers should be continued, although they should be used with caution.

In the reported clinical trials, the incidence of significant QT prolongation, defined as a mean QTc interval of greater than 500 milliseconds, was less than 1% in patients treated with Levalbuterol HCI Inhalation Solution.

Levalbuterol HCI Inhalation Solution should be administered with extreme caution to patients who have recently used intravenous or oral diuretics. Patients in whom hypokalemia is suspected on the basis of clinical symptoms or who have evidence of hypokalemia should also be carefully observed for signs of hypokalemia before being treated with Levalbuterol HCI Inhalation Solution.

The expected symptoms with overdosage are those of excessive beta-adrenergic receptor stimulation and/or occurrence or exaggeration of any of the adverse events listed in WARNINGS and PRECAUTIONS. Levalbuterol HCI Inhalation Solution should be administered with extreme caution to patients who have recently used intravenous or oral diuretics. Patients in whom hypokalemia is suspected on the basis of clinical symptoms or who have evidence of hypokalemia should also be carefully observed for signs of hypokalemia before being treated with Levalbuterol HCI Inhalation Solution.

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