Diabetes Mellitus

If necessary during surgery, the effects of beta-adrenergic blocking agents may be reversed by sufficient doses of isoproterenol or, in restarting and maintaining the heartbeat has also been reported. For these reasons, in patients undergoing elective surgery, beta-adrenergic receptor blocking agents have been subject to protracted severe hypotension during anesthesia. Difficulty in generating a sufficient heart rate necessary for maintenance of cardiac function has been observed. Cardiac arrest may result if the heart rate falls below the threshold below which the patient can be maintained. Beta-blocker-induced bradycardia in the beagle dog is dose-dependent and is observed in normal and chronically treated animals. A dose of 0.5 mg/kg body weight can reduce heart rate to approximately 100 beats/min. The effect is dose-dependent; in general, a dose doubling can be expected to reduce heart rate by an additional 20-30 beats/min. The lower limit of the dose required to produce bradycardia is not known. When the dose is increased, bradycardia usually develops slowly and is often reversible by discontinuation of the drug.

Levobunolol ophthalmic solution, USP is a noncardioselective beta-adrenoceptor blocking agent for ophthalmic use. Levobunolol HCl is a hygroscopic, white to off-white, polymorphic, crystalline material. It is the (–)-enantiomer of a naturally occurring, racemic mixture of levobunolol (levobunolol HCl). It is sold as a 0.5% solution of levobunolol HCl 0.5% strength units. Each mL of solution contains levobunolol HCl USP, 5 mg; sodium chloride; sodium metabisulfite; sodium phosphate, 9.0 mg; water; and a yellow high density polystyrene cap. The solution is intended for topical ophthalmic use.

Levobunolol ophthalmic solution USP sterile should be used with caution in patients with known hypersensitivity to any of the components. Allergic reactions to topical beta-adrenergic blocking agents have occurred rarely, usually limited to conjunctivitis or transient irritation. There have been isolated reports of severe reactions, including fatalities, which may be associated with the use of topical beta-adrenergic blocking agents. The potential for severe or fatal reactions increases with concomitant use of other medications known to produce a hypersensitivity reaction.

Levobunolol HCl ophthalmic solution USP and all forms of ophthalmic solutions, including contact lenses, are potentially ocular irritants. In addition to the potential for systemic absorption, eye drops can cause local irritation and discomfort, which may impair visual acuity. Local irritation and discomfort may also result in ocular irritation from mechanical debris or infectious keratitis. Care should be taken to avoid contamination of the eyes while using beta-adrenergic receptor blocking agents.

Levobunolol HCl ophthalmic solution may be administered by a prescriber, a trained lay person, or a properly instructed patient.

The most common signs and symptoms to be expected with overdosage with administration of a systemic beta-blocking agent include bradycardia, hypotension, and heart block. All patients should be observed for the development of signs of congestive heart failure and angina pectoris. Treatment consists of symptomatic and supportive therapy. Treatment with atropine may be helpful in patients with signs of symptomatic bradycardia. Beta-blocking agents may potenti‌aly block the hypoglycemia response to insulin or oral hypoglycemic agents. A severe, life-threatening reaction appears to be more likely to occur in diabetic patients (especially those with labile diabetes) who are receiving insulin or oral hypoglycemic agents. In patients with known hypersensitivity to insulin, monitoring of blood glucose concentration is recommended.

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