

ISOPTO[®] CARBACHOL

Carbachol Eye Drops 1.5% & 3.0%

Presentation

ISOPTO CARBACHOL is a cholinergic prepared as a sterile topical ophthalmic solution.

Each mL contains: Active: Carbachol 1.5% or 3.0%. Preservative: Benzalkonium Chloride 0.005%. Vehicle: Hydroxypropyl Methylcellulose 1.0%. Inactive: Boric Acid, Sodium Chloride, Sodium Borate, Purified Water.

Uses

Actions

A cholinergic (parasympathomimetic) agent, Carbachol has a double action, it not only stimulates the motor endplate, of the muscle cell, as do all cholinesters, but it also partially inhibits cholinesterase.

Pharmacokinetics

Unknown.

Indications

To reduce intraocular pressure. May be used to control intraocular pressure where control by pilocarpine has been lost or in cases of pilocarpine sensitivity.

Dosage and Administration

Instill two drops topically in the eye(s) up to three times daily or as indicated by physician. For adult use only.

Contraindications

Miotics are contraindicated where constriction is undesirable such as acute iritis. Contraindicated in those persons showing hypersensitivity to any component of this preparation.

Warnings and Precautions

For topical use only. Not for injection.

Carbachol should be used with caution in the presence of corneal abrasion to avoid- excessive penetration which can produce systemic toxicity; and in patients with acute cardiac failure, bronchial asthma, active peptic ulcer, hyperthyroidism, gastrointestinal spasm, urinary tract obstruction, Parkinson's disease, recent myocardial infarct, systemic hypertension or hypotension. As with all miotics, retinal detachment has been reported when used in certain susceptible individuals. The causal relationship has not been established.

Information for Patients

Patients should be instructed to avoid overdose.

The miosis usually causes difficulty in dark adaptation. Patient should be advised to exercise caution in night driving and other hazardous occupations in poor light. Do not touch dropper tip to any surface, as this may contaminate the solution.

If patients continue to wear soft (hydrophilic) contact lenses while under treatment with ISOPTO CARBACHOL, they should remove their lens(es) *prior* to instilling ISOPTO CARBACHOL in the affected eye(s) and should not replace their lens(es) until 15 minutes after instillation of the eye drops.

Carcinogenesis, Mutagenesis, Impairment of Fertility

There have been no long-term studies done using carbachol in animals to evaluate carcinogenic potential.

Pregnancy**Pregnancy Category C.**

Animal reproduction studies have not been conducted with carbachol. It is also not known whether carbachol can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Carbachol should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when carbachol is administered to a nursing woman.

Adverse Effects

Transient symptoms of stinging and burning may occur. This preparation is capable of producing systemic symptoms of a cholinesterase inhibitor even when the epithelium is intact. Transient ciliary and conjunctival injection, headache, and ciliary spasm with resultant temporary decrease of visual acuity may occur. Salivation, syncope, cardiac arrhythmia, gastrointestinal cramping, vomiting, asthma, hypotension, diarrhea, frequent urge to urinate, increased sweating, and irritation of eyes may occur.

Interactions

Unknown.

Overdosage

Atropine should be administered parenterally (for dosage refer to Goodman & Gilman or other pharmacology reference).

Pharmaceutical Precautions

Store ISOPTO CARBACHOL Eye Drops below 25°C. Keep the container tightly closed. Contents should be discarded four weeks after opening.

Medicine Classification

Prescription Medicine.

Package Quantities

Eye Drops, 1.5% and 3%, 15 mL.

Further Information

Nil.

Name and Address

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Date of Preparation

1st December 2007

ICarbachol_NZ/DS-#2

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