HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Isopto® Carpine safely and effectively. See full prescribing information for Isopto® Carpine.

Indications and Usage

Isopto® Carpine (pilocarpine hydrochloride ophthalmic solution) 1%, 2% and 4% are indicated for:

1.1 Reduction of Elevated Intraocular Pressure (IOP) in Patients with Open-Angle Glaucoma or Ocular Hypertension

1.2 Management of Acute Angle-Closure Glaucoma

1.3 Prevention of Postoperative Elevated IOP

1.4 Induction of Miosis

1.5 Treatment of Accommodative Spasm

1.6 Management of Acute Angle-Closure Glaucoma

1.7 Glaucoma or Ocular Hypertension

1.8 Induction of Miosis

1.9 Use of Other Topical Ophthalmic Medications

1.10 Use inPediatric Patients

2.1.1 Reduction of Elevated Intraocular Pressure (IOP) in Patients with Open-Angle Glaucoma or Ocular Hypertension

2.1.2 Management of Acute Angle-Closure Glaucoma

2.1.3 Prevention of Postoperative Elevated IOP

2.1.4 Induction of Miosis

2.1.5 Use with Other Topical Ophthalmic Medications

2.2 Management of Acute Angle-Closure Glaucoma

2.3 Prevention of Postoperative Elevated IOP Associated with Laser Surgery

2.4 Induction of Miosis

2.5 Use with Other Topical Ophthalmic Medications

Dosage and Administration

One drop of Isopto® Carpine 1%, 2% or 4% should be applied topically in the eye(s) up to four times daily or with pilocarpine 1%, 1.75% or 2% in fixed combination with an appropriate sympathomimetic or hyperosmotic agent. The objective is to achieve a therapeutic dose within five minutes of instillation that produces a response that is adequate for the patient. The dose used should be based on the severity of the condition and the patient's response. For the induction of miosis, patients should be instructed to apply the drops at 15 to 60 minutes prior to surgery. The duration of action of Isopto® Carpine in pediatric patients is comparable to that seen in adult patients.

10 OVERDOSAGE

Systemic toxicity following topical ocular administration of pilocarpine is rare, but accumulation of the drug may result in toxicity in patients who are sensitive to pilocarpine. Pilocarpine can cause significant symptoms and signs including salivation, sweating, tachycardia, flushing, and a decrease in blood pressure. In moderate overdosage, spontaneous recovery is to be expected and is aided by intravenous fluids to compensate for dehydration. For patients demonstrating severe poisoning, the use of atropine to block the effects of pilocarpine should be considered.

11 DESCRIPTION

Isopto® Carpine (pilocarpine hydrochloride ophthalmic solution) is a muscarinic cholinergic agonist prepared as a sterile ophthalmic solution and to wait 10 minutes after dosing before reinserting their contact lenses.

6 ADVERSE REACTIONS

Preservative: benzalkonium chloride 0.11%.

6.1 Reports of poisoning and overdosage

Carcinogenicity, Mutagenicity, Impairment of fertility

6.1.4 Induction of Miosis

6.1.5 Treatment of Accommodative Spasm

6.1.6 Management of Acute Angle-Closure Glaucoma

6.1.7 Glaucoma or Ocular Hypertension

6.1.8 Induction of Miosis

6.1.9 Use of Other Topical Ophthalmic Medications

6.2 Use inPediatric Patients

6.3 Use following exposure to pilocarpine, patients may be instructed to perform punctal occlusion for 2 minutes after instillation of Isopto® Carpine ophthalmic solution.

6.4 Contraindications

6.5 Contact Lens Wear

6.6 Adverse Reactions

6.7 Use inPediatric Patients

6.8 Use of Other Topical Ophthalmic Medications

6.10 Preservative

7 WARNINGS AND PRECAUTIONS

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Nursing Mothers

8.3 Geriatric Use

8.4 Pediatric Use

9 CLINICAL STUDIES

9.1 Efficacy

9.2 Safety

9.3 Pharmacokinetics

10 OVERDOSAGE

11 DESCRIPTION

12.1 Mechanism of Action

12.2 Clinical Pharmacokinetics

12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

14 CLINICAL STUDIES

15.2 Night Driving

15.1 Avoiding Contamination of the Product

15.3 Contact Lens Wear

15.4 Primary Congenital Glaucoma

15.5 Contact Lens Wear

17.2 Night Driving

17.1 Avoiding Contamination of the Product

17.3 Accommodative Spasm

17.4 Contact Lens Wear

17.5 Concomitant Topical Ocular Therapy

17.6 Systemic Exposure

2.2 Management of Acute Angle-Closure Glaucoma

2.3 Prevention of Postoperative Elevated IOP Associated with Laser Surgery

2.4 Induction of Miosis

2.5 Use with Other Topical Ophthalmic Medications

2.6 Use in Pediatric Patients

2.7 Use following exposure to pilocarpine, patients may be instructed to perform punctal occlusion for 2 minutes after instillation of Isopto® Carpine ophthalmic solution.

2.8 Use inPediatric Patients

2.9 Use of Other Topical Ophthalmic Medications

2.10 Use inPediatric Patients

2.11 Use with Other Topical Ophthalmic Medications

3 CONTRAINDICATIONS

3.1 Carcinogenesis, Mutagenesis, Impairment of fertility

3.2 Contraindication

3.3 Contraindication

4 DOSAGE AND STRENGTHS

4.1 Solution containing 1% (10 mg/mL), 2% (20 mg/mL) or 4% (40 mg/mL) pilocarpine hydrochloride (3)

4.2 DOSAGE AND ADMINISTRATION

4.3 DOSAGE FORMS AND STRENGTHS

5 WARNINGS AND PRECAUTIONS

5.1 Poor Illumination

5.2 Pre-existing Retinal Disease

5.3 Iris

5.4 Primary Congenital Glaucoma

5.5 Contact Lens Wear

6 ADVERSE REACTIONS

6.1 Reports of poisoning and overdosage

6.2 Use inPediatric Patients

6.3 Use following exposure to pilocarpine, patients may be instructed to perform punctal occlusion for 2 minutes after instillation of Isopto® Carpine ophthalmic solution.