

NDA 12-583/S-037

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[Company Logo]

**OPHTHETIC<sup>®</sup>**

**(proparacaine HCl ophthalmic solution) 0.5%**

### DESCRIPTION

OPHTHETIC<sup>®</sup> (proparacaine HCl ophthalmic solution) 0.5% is a topical local anesthetic for ophthalmic use.

### Structural Formula:

[structure]

### Chemical Name:

Benzoic acid, 3-amino-4-propoxy-, 2-(diethylamino)ethyl ester, monohydrochloride.

### Contains:

**Active:** proparacaine HCl 0.5%

**Preservative:** benzalkonium chloride (0.01%). **Inactives:** glycerin; sodium chloride; and purified water. The pH may be adjusted with hydrochloric acid and/or sodium hydroxide.

### CLINICAL PHARMACOLOGY

OPHTHETIC<sup>®</sup> ophthalmic solution is a rapidly-acting topical anesthetic, with induced anesthesia lasting approximately 10-20 minutes.

### INDICATIONS AND USAGE

OPHTHETIC<sup>®</sup> ophthalmic solution is indicated for procedures in which a topical ophthalmic anesthetic is indicated: corneal anesthesia of short duration, e.g. tonometry, gonioscopy, removal of corneal foreign bodies, and for short corneal and conjunctival procedures.

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## CONTRAINDICATIONS

OPHTHETIC<sup>®</sup> ophthalmic solution should be considered contraindicated in patients with known hypersensitivity to any of the ingredients of this preparation.

## WARNINGS

Prolonged use of a topical ocular anesthetic is not recommended. It may produce permanent corneal opacification with accompanying visual loss.

## PRECAUTIONS

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term studies in animals have not been performed to evaluate carcinogenic potential, mutagenicity, or possible impairment of fertility in males or females.

**Pregnancy: Pregnancy Category C:** Animal reproduction studies have not been conducted with OPTHETIC<sup>®</sup> (proparacaine hydrochloride ophthalmic solution) 0.5%. It is also not known whether proparacaine hydrochloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Proparacaine hydrochloride should be administered 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 proparacaine hydrochloride is administered to a nursing mother.

**Pediatric Use:** Safety and effectiveness of proparacaine HCl Ophthalmic Solution in pediatric patients have been established. Use of proparacaine HCl is supported by evidence from adequate and well-controlled studies in adults and children over the age of twelve, and safety information in neonates and other pediatric patients.

**Geriatric use:** No overall clinical differences in safety or effectiveness have been observed between the elderly and other adult patients.

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## ADVERSE REACTIONS

Occasional temporary stinging, burning and conjunctival redness may occur with the use of proparacaine. A rare, severe, immediate-type, apparently hyperallergic corneal reaction characterized by acute, intense and diffuse epithelial keratitis, a gray, ground glass appearance, sloughing of large areas of necrotic epithelium, corneal filaments and, sometimes, iritis with descemetitis has been reported.

Allergic contact dermatitis from proparacaine with drying and fissuring of the fingertips has also been reported.

## DOSAGE AND ADMINISTRATION

Usual Dosage: Removal of foreign bodies and sutures, and for tonometry: 1 to 2 drops (in single instillations) in each eye before operating.

Short corneal and conjunctival procedures: 1 drop in each eye every 5 to 10 minutes for 5 to 7 doses.

**Note:** OPTHETIC<sup>®</sup> should be clear to straw-color. If the solution becomes darker, discard the solution.

## HOW SUPPLIED

OPHTHETIC<sup>®</sup> (proparacaine hydrochloride ophthalmic solution) 0.5% is supplied in plastic dropper bottles in the following size:

15 mL – NDC 11980-048-15

Bottle must be stored in unit carton to protect contents from light. Store bottles under refrigeration at 2° to 8°C (36° to 46°F).

**Rx Only**

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Carton, 15 mL, 0.5%

63095US10H	Lot No: Exp:	011269	<p><b>[Company logo]® No 0048</b> <b>ALLERGAN 4424X</b></p> <p><b>NDC 11980-048-15</b> <b>15 mL</b></p> <p><b>OPHTHETIC®</b> (proparacaine HCl ophthalmic solution) 0.5%</p> <p>Sterile</p>
<p><b>[Company logo]®</b> <b>ALLERGAN</b></p> <p><b>NDC 11980-048-15</b> <b>15 mL</b></p> <p><b>OPHTHETIC®</b> (proparacaine HCl ophthalmic solution) 0.5%</p> <p>Sterile      <b>Rx Only</b></p>	<p><b>[Company logo]®</b> <b>ALLERGAN</b></p> <p><b>NDC 11980-048-15</b> <b>15 mL</b></p> <p><b>OPHTHETIC®</b> (proparacaine HCl ophthalmic solution) 0.5%</p> <p>Sterile      <b>Rx Only</b></p>	Bar code	<p><b>CONTAINS: Active:</b> proparacaine HCl 0.5%. <b>Preservative:</b> benzalkonium chloride (0.01%). <b>Inactives:</b> glycerin; sodium chloride; and purified water. The pH may be adjusted with hydrochloric acid and/or sodium hydroxide. <b>USUAL DOSAGE:</b> Refer to accompanying literature. <b>Note:</b> Bottle must be stored in unit carton to protect contents from light. Store bottles under refrigeration 2° to 8°C (36° to 46°F). OPHTHETIC® should be clear to straw-color. If the solution becomes darker, discard the solution. <b>NOT FOR INJECTION.</b> <b>Allergan Inc.,</b> Irvine, CA 92612, U.S.A. ©2000 Allergan, Inc. ®Registered trademarks of Allergan, Inc.</p>

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Container Label Bottles, 15 mL, 0.5%

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