

**PROPARACAINE HYDROCHLORIDE - proparacaine hydrochloride solution/ drops  
Sandoz Inc.**

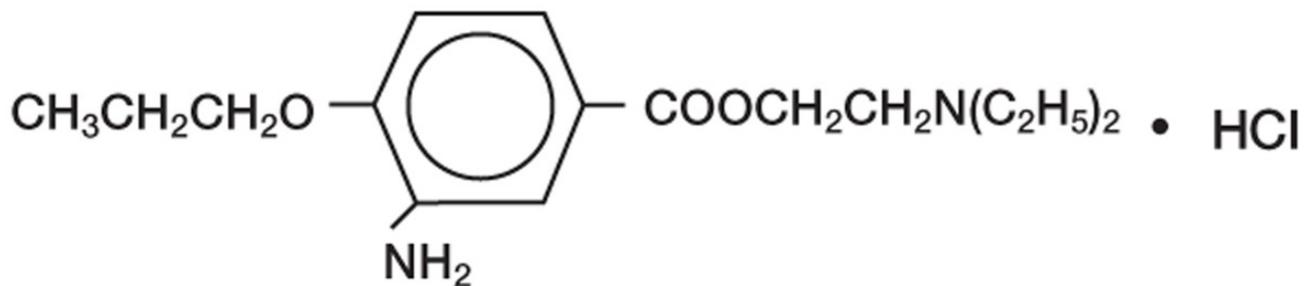
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**Proparacaine Hydrochloride  
Ophthalmic Solution USP, 0.5%**

**DESCRIPTION**

Proparacaine hydrochloride ophthalmic solution 0.5% is a topical local anesthetic for ophthalmic use. The active ingredient is represented by the structural formula:

Established name: Proparacaine Hydrochloride

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



Molecular Weight: 330.85

Each mL contains: **Active:** proparacaine hydrochloride 5mg 0.5%. **Preservative:** benzalkonium chloride (0.01%). **Inactives:** glycerin; and purified water. The pH may be adjusted with hydrochloric acid and/or sodium hydroxide.

**CLINICAL PHARMACOLOGY**

Proparacaine hydrochloride ophthalmic solution is a rapidly-acting topical anesthetic, with induced anesthesia lasting approximately 10-20 minutes.

**INDICATIONS AND USAGE**

Proparacaine hydrochloride 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.

**CONTRAINDICATIONS**

Proparacaine hydrochloride ophthalmic solution should be considered contraindicated in patients with known hypersensitivity to any of the ingredients of this preparation.

**WARNINGS**

NOT FOR INJECTION - FOR TOPICAL OPHTHALMIC USE ONLY. 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 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 woman.

### **Pediatric Use**

Safety and effectiveness of proparacaine hydrochloride ophthalmic solution in pediatric patients have been established. Use of proparacaine hydrochloride 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

## **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:** Proparacaine hydrochloride ophthalmic solution should be clear to straw-color. If the solution becomes darker, discard the solution.

## **HOW SUPPLIED**

Proparacaine hydrochloride ophthalmic solution 0.5% is supplied in 15 mL DROP-TAINER\* dispensers.

**NDC 61314-016-01**

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

**Rx Only**

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc., at 1-800-525-8747 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

\*DROP-TAINER is a registered trademark of Alcon Research, Ltd.

Rev. June 2012

**SANDOZ**

Manufactured by  
Alcon Laboratories, Inc.  
Fort Worth, Texas 76134 for  
Sandoz Inc.  
Princeton, NJ 08540  
Printed in USA

**9007253-1011**

**PRINCIPAL DISPLAY PANEL**

**NDC 61314-016-01**

**Proparacaine Hydrochloride Ophthalmic Solution, USP**

**0.5%**

**Rx only**

STERILE

**15 mL**

**PRECAUTION:** NOT FOR INJECTION. FOR TOPICAL OPHTHALMIC USE ONLY. Do not touch dropper tip to any surface, as this may contaminate the solution.

**USUAL DOSAGE:** 1 or 2 drops.

Read enclosed insert.

Bottles must be stored in unit carton to protect from light.

**STORAGE:** Store between 2°-8°C (36°-46°F). Proparacaine hydrochloride ophthalmic solution should be clear to straw-color. If the solution becomes darker, discard the solution.

**INGREDIENTS: Each mL contains:**

**Active:** proparacaine hydrochloride 5 mg (0.5%).

**Preservative:** benzalkonium chloride 0.01%.

**Inactives:** glycerin, hydrochloric acid and/or sodium hydroxide (to adjust pH), purified water.

MANUFACTURED BY ALCON LABORATORIES, INC.

Manufactured by  
Alcon Laboratories, Inc.  
Fort Worth, Texas 76134 for  
Sandoz Inc.  
Princeton, NJ 08540

Printed in USA

**9012981-0216**

Rev. 06/2012



NDC 61314-016-01

**Proparacaine Hydrochloride Ophthalmic Solution, USP**

**0.5%**

**Rx only**

**STERILE**

**15 mL**

## SANDOZ

### INGREDIENTS: Each mL contains:

**Active:** proparacaine hydrochloride 5 mg (0.5%).

**PRECAUTION:** NOT FOR INJECTION. FOR TOPICAL OPHTHALMIC USE ONLY. Do not touch dropper tip to any surface as this may contaminate the solution.

**USUAL DOSAGE:** 1 or 2 drops.  
Read enclosed insert.

**STORAGE:** Store between 2°-8°C (36°-46°F).

**Bottles must be stored in unit carton to protect from light.**

Proparacaine hydrochloride ophthalmic solution should be clear to straw-color. If the solution becomes darker, discard the solution.

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Alcon Laboratories, Inc.  
Fort Worth, Texas 76134 for  
Sandoz Inc.  
Princeton, NJ 08540  
Rev. 04-2012

### LOT/EXP.:

H14233-0216

**INGREDIENTS:** Each mL contains: **Active:** proparacaine hydrochloride 5 mg (0.5%).

**PRECAUTION:** NOT FOR INJECTION. FOR TOPICAL OPHTHALMIC USE ONLY. Do not touch dropper tip to any surface as this may contaminate the solution.

**USUAL DOSAGE:** 1 or 2 drops. Read enclosed insert.

**STORAGE:** Store between 2° to 8°C (36° to 46°F).  
**Bottles must be stored in unit carton to protect from light.**

NDC 61314-016-01

**Proparacaine Hydrochloride Ophthalmic Solution, USP**

**0.5%**

**Rx only** STERILE 15 mL

**SANDOZ**

Proparacaine hydrochloride ophthalmic solution should be clear to straw-color. If the solution becomes darker, discard the solution.

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Rev. 03/2016

LOT: H14233-0216

EXP:

## PROPARACAINE HYDROCHLORIDE

proparacaine hydrochloride solution/ drops

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:61314-016
<b>Route of Administration</b>	OPHTHALMIC		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
PROPARACAINE HYDROCHLORIDE (UNII: U96OL57GOY) (PROPARACAINE - UNII:B4OB0JH1X)	PROPARACAINE HYDROCHLORIDE	5 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61314-016-01	1 in 1 CARTON	06/05/2000	
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA080027	06/05/2000	

**Labeler** - Sandoz Inc. (005387188)**Registrant** - Alcon Laboratories, Inc. (008018525)**Establishment**

Name	Address	ID/FEI	Business Operations
Alcon Research Ltd		007672236	manufacture(61314-016)

Revised: 2/2017

Sandoz Inc.