PROPARACAINE HYDROCHLORIDE- proparacaine hydrochloride solution/ drops
Bausch & Lomb Incorporated

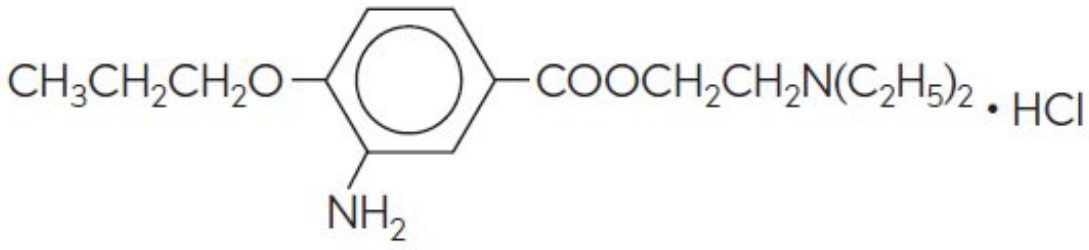
Proparacaine Hydrochloride
Ophthalmic Solution, USP
0.5%
(Sterile)
Rx only

DESCRIPTION

Proparacaine hydrochloride ophthalmic solution USP, 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: 330.86

Each mL contains:

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

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 is contraindicated in patients with known hypersensitivity to any of the ingredients of this preparation.

WARNINGS

NOT FOR INJECTION INTO THE EYE - 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

Animal reproduction studies have not been conducted with proparacaine hydrochloride ophthalmic solution USP, 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 of 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 been reported.

To report SUSPECTED ADVERSE REACTIONS, contact Bausch & Lomb Incorporated at 1-800-553-5340 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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 USP, 0.5% should be clear, colorless to faint yellow color. If the solution becomes darker, discard the solution.

FOR TOPICAL OPHTHALMIC USE ONLY

HOW SUPPLIED

Proparacaine hydrochloride ophthalmic solution USP, 0.5% is supplied in a plastic bottle with a controlled drop tip and a white polypropylene cap in the following size:

NDC 24208-730-06 15 mL bottle

Storage:

Refrigerate at 2°C to 8°C (36°F to 46°F). Protect from light. Keep tightly closed.

DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.

Keep out of reach of children.

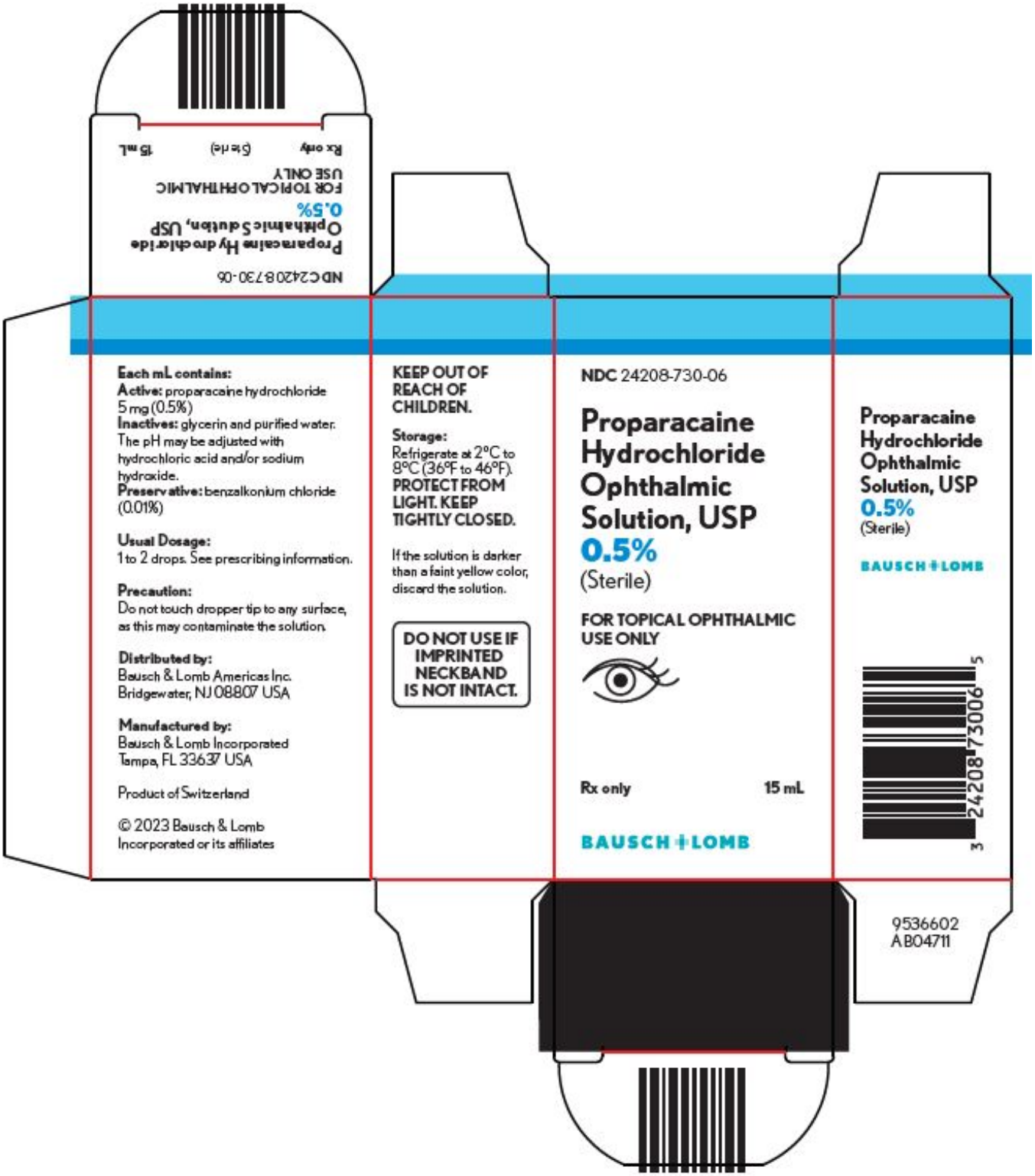
Distributed by:
Bausch & Lomb Americas Inc.
Bridgewater, NJ 08807 USA

Manufactured by:
Bausch & Lomb Incorporated
Tampa, FL 33637 USA

Revised: September 2023

9114405 **(Folded)**
9114505 **(Flat)**

PRINCIPAL DISPLAY PANEL-Carton



NDC 24208-730-06

Proparacaine Hydrochloride Ophthalmic Solution, USP

0.5%
(Sterile)

FOR TOPICAL OPHTHALMIC USE ONLY

Rx only

15 mL

BAUSCH + LOMB

9536602

AB04711

PROPARACAINE HYDROCHLORIDE

proparacaine hydrochloride solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:24208-730
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PROPARACAINE HYDROCHLORIDE (UNII: U96OL57GOY) (PROPARACAINE - UNII:B4OB0JHI1X)	PROPARACAINE HYDROCHLORIDE	5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:24208-730-06	1 in 1 CARTON	09/29/1995	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA040074	09/29/1995	

Labeler - Bausch & Lomb Incorporated (196603781)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(24208-730)

Revised: 9/2023 Bausch & Lomb Incorporated