PROPARACAINE HYDROCHLORIDE- proparacaine hydrochloride solution/ drops
REMEDYREPACK INC.

Proparacaine Hydrochloride

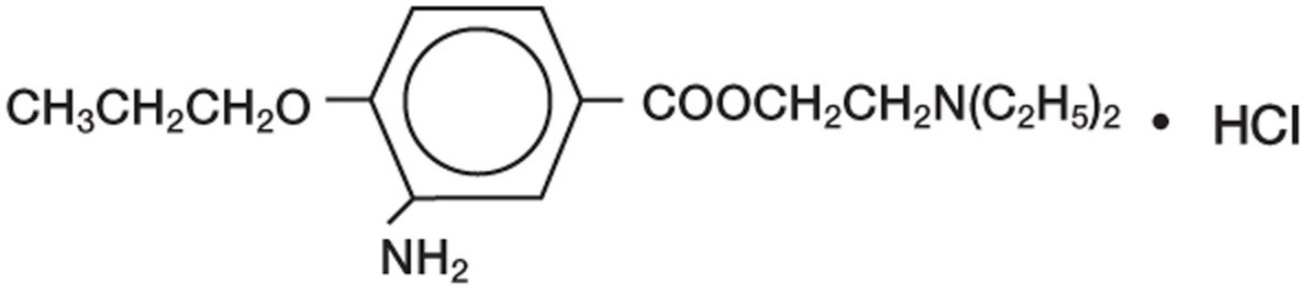
Ophthalmic Solution USP, 0.5%

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: 70518-3408-00

PACKAGING: 1 in 1 CARTON, 15 mL in 1 BOTTLE TYPE 0

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

Repackaged and Distributed By:

Remedy Repack, Inc.

625 Kolter Dr. Suite #4 Indiana, PA 1-724-465-8762

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DRUG: Proparacaine Hydrochloride

GENERIC: Proparacaine Hydrochloride

DOSAGE: SOLUTION/ DROPS

ADMINSTRATION: OPHTHALMIC

NDC: 70518-3408-0

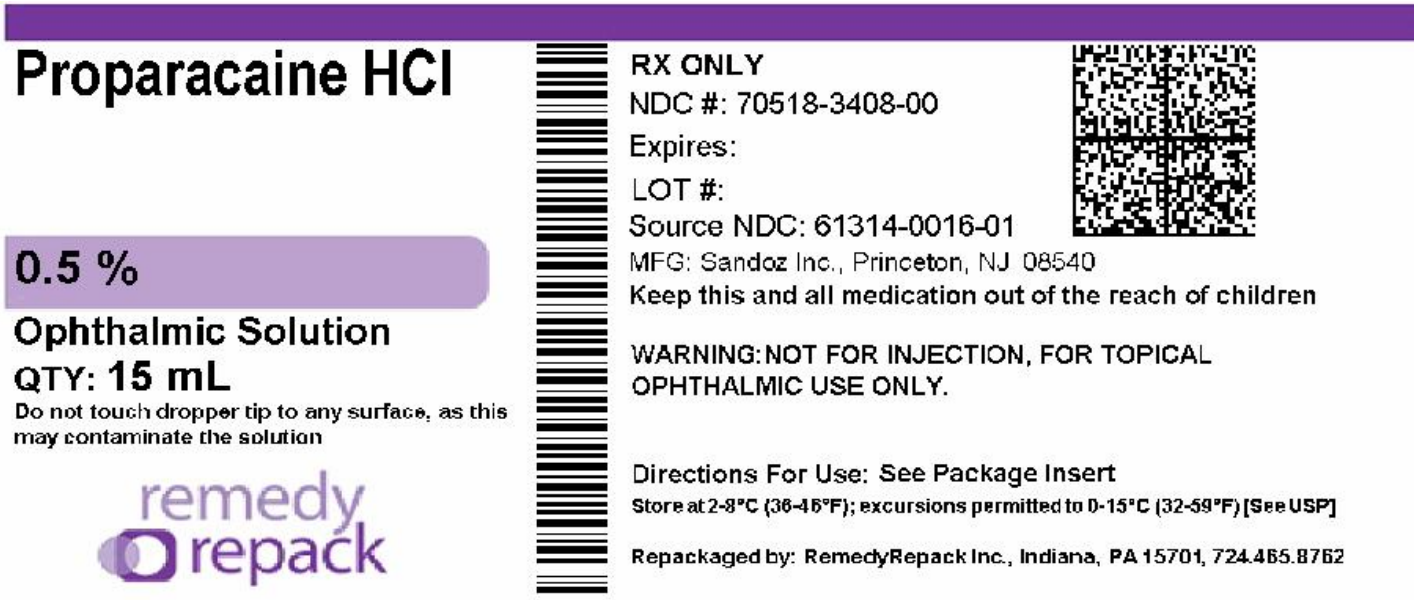
PACKAGING: 15 mL in 1 BOTTLE

OUTER PACKAGING: 1 in 1 CARTON

ACTIVE INGREDIENT(S):
- PROPARACAINE HYDROCHLORIDE 5mg in 1mL

INACTIVE INGREDIENT(S):
- BENZALKONIUM CHLORIDE

- GLYCERIN
- WATER
- HYDROCHLORIC ACID
- SODIUM HYDROXIDE



PROPARACAINE HYDROCHLORIDE

proparacaine hydrochloride solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70518-3408(NDC:61314-016)
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)	
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:70518-3408-0	1 in 1 CARTON	04/08/2022	
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	04/08/2022	

Labeler - REMEDYREPACK INC. (829572556)

Revised: 1/2024 REMEDYREPACK INC.