PROPARACAINE HYDROCHLORIDE - proparacaine hydrochloride solution/ drops
Micro Labs Limited

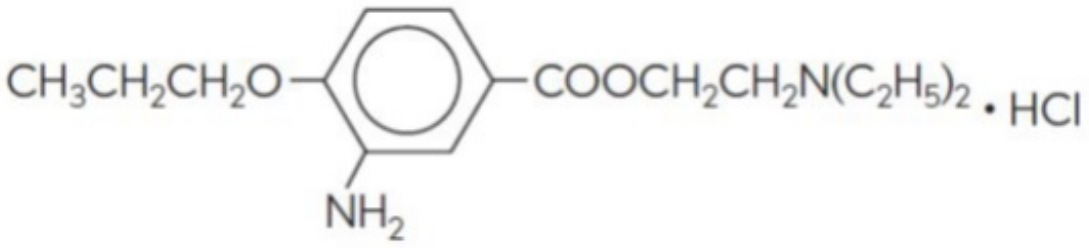
PROPARACAINE HYDROCHLORIDE OPHTHALMIC SOLUTION USP, 0.5% (Sterile)
Rx only

DESCRIPTION

Proparacaine hydrochloride ophthalmic solution USP, 0.5% is a local anesthetic for ophthalmic instillation. Each mL of sterile aqueous solution contains active ingredient: proparacaine hydrochloride 5 mg (0.5%) and inactive ingredients: glycerin (tonicity agent), benzalkonium chloride, 0.01% (preservative) and water for injection (vehicle). The pH may be adjusted with hydrochloric acid and/or sodium hydroxide. At the time of manufacture, the air in the container is replaced by nitrogen.

Proparacaine hydrochloride is designated chemically as 2-(Diethylamino) ethyl 3-amino-4-propoxybenzoate monohydrochloride.

Graphic formula:



$C_{16}H_{26}N_2O_3$•HCl MW 330.85 CAS-5875-06-9

CLINICAL PHARMACOLOGY

Proparacaine hydrochloride ophthalmic solution is a rapid acting local anesthetic suitable for ophthalmic use. With a single drop, the onset of anesthesia occurs in approximately 13 seconds and persists for 15 minutes or longer.

The main site of anesthetic action is the nerve cell membrane where proparacaine interferes with the large transient increase in the membrane permeability to sodium ions that is normally produced by a slight depolarization of the membrane. As the anesthetic action progressively develops in a nerve, the threshold for electrical stimulation gradually increases and the safety factor for conduction decreases; when this action is sufficiently well developed, block of conduction is produced.

The exact mechanism whereby proparacaine and other local anesthetics influence the

permeability of the cell membrane is unknown; however, several studies indicate that local anesthetics may limit sodium ion permeability by closing the pores through which the ions migrate in the lipid layer of the nerve cell membrane. This limitation prevents the fundamental change necessary for the generation of the action potential.

INDICATIONS AND USAGE

Proparacaine Hydrochloride Ophthalmic solution is indicated for topical anesthesia in ophthalmic practice. Representative ophthalmic procedures in which the preparation provides good local anesthesia include measurement of intraocular pressure (tonometry), removal of foreign bodies and sutures from the cornea, conjunctival scraping in diagnosis and gonioscopic examination; it is also indicated for use as a topical anesthetic prior to surgical operations such as cataract extraction.

CONTRAINDICATIONS

This preparation is contraindicated in patients with known hypersensitivity to any component of the solution.

WARNINGS

For topical ophthalmic use only.

Prolonged use of a topical ocular anesthetic may produce permanent corneal opacification with accompanying loss of visual.

Proparacaine hydrochloride ophthalmic solution is indicated for administration under the direct supervision of a

healthcare provider. Proparacaine hydrochloride ophthalmic solution is not intended for patient self-administration.

PRECAUTIONS

General

Proparacaine should be used cautiously and sparingly in patients with known allergies, cardiac disease, or hyperthyroidism. The long-term toxicity of proparacaine is unknown; prolonged use may possibly delay wound healing. Although exceedingly rare with ophthalmic application of local anesthetics, it should be borne in mind that systemic toxicity (manifested by central nervous system stimulation followed by depression) may occur.

Protection of the eye from irritating chemicals, foreign bodies and rubbing during the period of anesthesia is very important. Tonometers soaked in sterilizing or detergent

solutions should be thoroughly rinsed with sterile distilled water prior to use. Patients should be advised to avoid touching the eye until the anesthesia has worn off.

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, 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

Pupillary dilation or cycloplegic effects have rarely been observed with proparacaine hydrochloride. The drug appears to be safe for use in patients sensitive to other local anesthetics, but local or systemic sensitivity occasionally occurs.

Instillation of proparacaine in the eye at recommended concentration and dosage usually produces little or no initial irritation, stinging, burning, conjunctival redness, lacrimation or increased winking. However, some local irritation and stinging may occur several

hours after the instillation. Rarely, a severe, immediate-type, apparently

hyperallergic corneal reaction may occur which includes 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. Allergic contact dermatitis with drying and fissuring of the fingertips has been reported.

Softening and erosion of the corneal epithelium and conjunctival congestion and hemorrhage have been reported.

To report SUSPECTED ADVERSE REACTIONS, contactMicro Labs USA, Inc.,at 1-855-839-8195 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

Deep anesthesia as in cataract extraction:

Instill 1 drop every 5 to 10 minutes for 5 to 7 doses.

Removal of sutures:

Instill 1 or 2 drops 2 or 3 minutes before removal of stitches.

Removal of foreign bodies:

Instill 1 or 2 drops prior to operating.

Tonometry:

Instill 1 or 2 drops immediately before measurement

HOW SUPPLIED

Proparacaine hydrochloride ophthalmic solution USP, 0.5% is supplied in a 3-piece white low density polyethylene S design container with natural low density polyethylene S design open nozzle and white color high density polyethylene S design cap with TSTR-tear off ring.

15 mL fill in 15 mL Container NDC 42571-497-57

Storage:

Refrigerate at 2° to 8° C. Keep bottle tightly closed. Store bottles in carton until empty to protect from light. If solution shows more than a faint yellow color, it should not be used.

Manufactured by:

Micro Labs Limited

Bangalore-560099, INDIA

Manufactured for:

Micro Labs USA, Inc.

Somerset, NJ 08873

Rev. 01/2025

MICROBIOLOGY SECTION

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 42571-497-57

Rx only
Proparacaine Hydrochloride Ophthalmic Solution, USP
0.5%

For eye use only
15 mL
Sterile
Micro Labs Limited

Pasting flap shall be un-varnished

NDC 42571-**497**-57

Proparacaine Hydrochloride Ophthalmic Solution, USP

0.5%

For eye use only

Rx Only

Sterile

MICRO LABS

15 mL

USC-ML14-090

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

Usual Dosage: 1 to 2 drops. See prescribing information.

Precaution: Do not touch dropper tip to any surface, as this may contaminate the solution.

Storage: Refrigerate at 2° to 8°C (36° to 46°F). **PROTECT FROM LIGHT. KEEP TIGHTLY CLOSED.**

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

If the solution is darker than a faint yellow color, discard the solution.

DO NOT USE IF THE SEAL IS BROKEN OR MISSING.

NDC 42571-**497**-57

Proparacaine Hydrochloride Ophthalmic Solution, USP

0.5%

For eye use only

Rx Only

Sterile

MICRO LABS

15 mL

Code: KR/DRUGS/KTK/28/357/2006

Manufactured by:
Micro Labs Limited
INDIA

Manufactured for:
Micro Labs USA, Inc.
Somerset, NJ 08873

Rev. 05/2025-01

N 3 42571 49757 6

NDC 42571-**497**-57 **Rx Only**

Proparacaine Hydrochloride Ophthalmic Solution, USP

0.5%

For eye use only

15 mL **Sterile**

PROPARACAINE HYDROCHLORIDE

proparacaine hydrochloride solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42571-497
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)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:42571-497-57	1 in 1 CARTON	02/01/2026	
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	ANDA219294	02/01/2026	

Labeler - Micro Labs Limited (862174955)

Establishment

Name	Address	ID/FEI	Business Operations
Micro Labs Limited		677600482	analysis(42571-497) , label(42571-497) , manufacture(42571-497) , pack(42571-497)

Revised: 10/2025 Micro Labs Limited