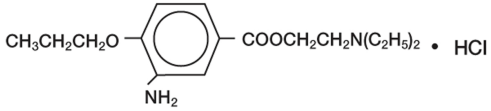
10302

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:** Proparacaine Hydrochloride 5 mg (0.5%). **Preservative:** Benzalkonium Chloride 0.1 mg (0.01%). **Inactives:** Glycerin as a stabilizer, Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH, and Water for Injection USP.

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



$C_{16}H_{26}N_2O_3$ •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
NOT FOR INJECTION INTO THE EYE - For topical ophthalmic use only.

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

Proparacaine ophthalmic solution is indicated for administration under the direct supervision of a healthcare provider. Proparacaine 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 of 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, contact Somerset Therapeutics, LLC at 1- 800-417-9175 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.

FOR TOPICAL OPHTHALMIC USE ONLY

HOW SUPPLIED

Proparacaine Hydrochloride Ophthalmic Solution USP, 0.5% is supplied as a sterile solution in a 15 mL white LDPE bottle with natural LDPE nozzle and white HDPE cap as follows:
NDC 70069-601-01, 15 mL fill in a 15 mL capacity bottle

Storage:
Refrigerate at 2° to 8° C (36°F to 46°F). 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.

Keep out of reach of children.

Manufactured for:
Somerset Therapeutics, LLC
Somerset, NJ 08873
Customer Care # 1-800-417-9175

Made in India
Code No.: KR/DRUGS/KTK/28/289/97

1201016

ST-PPC/P/01

Revised: July, 2024

SOMERSET THERAPEUTICS LIMITED				ARTWORK APPROVAL FORM			
Product	Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%			**Style:**	NA		
Specification:	Printed on 56-60 GSM Maplitho Paper **Ink : *Siegwerk*** (VEGA SPRINT PROCESS BLACK -60-922415-9) **/*Toyo*** (TK ARIS BLACK) (**Benzophenone free**)			**Colours:**	■ Black		
				Dimension:	Open: 125 x 200 mm (LxW) Folded: 125 x 25 mm		
Item Code	1201016	**Remarks** NA		**No of Folds: (only for PIL)**	(3 folds)	**Artwork Print Scaled to**	NA
Prepared by PDD	**Verified by FD**	**Approved by Regulatory Affairs**	**Checked by Packing**	**Checked by QA**		**Approved by QA**	

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