TETRACAINE HYDROCHLORIDE- tetracaine hydrochloride solution
REMEDYREPACK INC.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

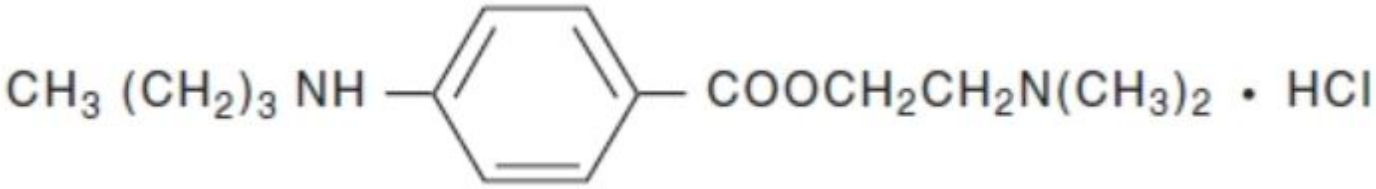
Tetracaine Hydrochloride Ophthalmic Solution USP, 0.5%

(Sterile)

Rx only

DESCRIPTION:

Tetracaine Hydrochloride is a sterile aqueous topical anesthetic ophthalmic solution. The active ingredient is represented by the chemical structure:



$C_{15}H_{24}N_2O_2 \cdot HCl$
Mol. wt. 300.83

Benzoic acid, 4-[butylamino]-, 2-[dimethylamino]ethyl ester, monohydrochloride.

EACH mL CONTAINS: ACTIVE: Tetracaine Hydrochloride 5 mg (0.5%); INACTIVES: Boric Acid, Potassium Chloride, Edetate Disodium and Purified Water. Sodium Hydroxide and/or Hydrochloric Acid may be added to adjust pH (3.7 - 6.0). PRESERVATIVE ADDED: Chlorobutanol 0.4%.

CLINICAL PHARMACOLOGY:

Topical anesthetics stabilize the neuronal membrane and prevent the initiation and transmission of nerve impulses, thereby effecting local anesthesia. The onset of anesthesia usually begins within 30 seconds and lasts a relatively short period of time.

INDICATIONS AND USAGE:

For procedures in which a rapid and short-acting topical ophthalmic anesthetic is indicated such as in tonometry, gonioscopy, removal of corneal foreign bodies, conjunctival scraping for diagnostic purposes, suture removal from the cornea, other short corneal and conjunctival procedures.

CONTRAINDICATIONS:

Should not be used by the patient without physician supervision, or in those persons showing hypersensitivity to any component of this preparation. This product should never be prescribed for the patient’s own use.

WARNINGS:

Prolonged use results in diminished duration of anesthesia and retarded healing. This may cause the drug to be used more frequently creating a “vicious circle.” Subsequent corneal infection and/or corneal opacification with accompanying permanent visual loss or corneal perforation may occur.

PRECAUTIONS:

FOR TOPICAL USE ONLY—NOT FOR INJECTION. To prevent contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding area with the dropper tip. Patient should be advised not to touch or rub the eye(s) until the effect of the anesthetic has worn off.

Information to the Patient:

After instillation of this product, the surface of the eye is insensitive and can be scratched without feeling it. Do not rub eye. Do not instill this product repeatedly because severe eye damage may occur.

NOTE:

DO NOT USE IF SOLUTION CONTAINS CRYSTALS, OR IS CLOUDY OR DISCOLORED.

ADVERSE REACTIONS:

Transient symptoms (signs) such as stinging, burning and conjunctival redness may occur. A rare, severe, immediate allergic cornea reaction has been reported, characterized by acute diffuse epithelial keratitis with filament formation and/or sloughing of large areas of necrotic epithelium, diffuse stromal edema, descemetitis and iritis.

DOSAGE AND ADMINISTRATION:

For tonometry and other procedures of short duration, instill one or two drops just prior to evaluation. For minor surgical procedures such as foreign body or suture removal, administer one to two drops every five to ten minutes for one to three instillations. For prolonged anesthesia as in cataract extraction, instill one or two drops in the eye(s) every five to ten minutes for three to five doses.

DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.

HOW SUPPLIED:

Tetracaine Hydrochloride Ophthalmic Solution USP, 0.5% is supplied in a plastic bottle with a controlled drop tip in the following size:

15 mL - NDC 69292-317-15

STORAGE:

Storage: Store between 15°-25°C (59°-77°F). KEEP TIGHTLY CLOSED.

KEEP OUT OF REACH OF CHILDREN.

Revised: December 2017

Manufactured for:

Amici Pharmaceuticals

Melville, NY 11747 USA

Manufactured by:

Bausch & Lomb Incorporated

Tampa, FL 33637 USA

9618100 (**Folded**)

9618000 (**Flat**)

DRUG: Tetracaine Hydrochloride

GENERIC: Tetracaine Hydrochloride

DOSAGE: SOLUTION

ADMINSTRATION: OPHTHALMIC

NDC: 70518-2224-0

PACKAGING: 15 mL in 1 BOTTLE, DROPPER

OUTER PACKAGING: 1 in 1 CARTON

ACTIVE INGREDIENT(S):

- TETRACAINE HYDROCHLORIDE 5mg in 1mL

INACTIVE INGREDIENT(S):

- BORIC ACID
- HYDROCHLORIC ACID
- SODIUM HYDROXIDE
- CHLOROBUTANOL
- EDETATE DISODIUM
- POTASSIUM CHLORIDE
- WATER

Tetracaine HCl

0.5%

5mg/1 mL Ophth Solu

QTY: 15

ID #: .

Expires:

NDC #: 70518-2224-00

Shape: .

LOT #:

Ref #: 69292-0317-15

MFG: Amici Pharmaceuticals, Melville, New York 11747

RX ONLY

Directions For Use: See Package Insert

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Repackaged by:
RemedyRepack Inc., Indiana, PA 15701, 1-724-465-8762

TETRACAINE HYDROCHLORIDE

tetracaine hydrochloride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70518-2224(NDC:69292-317)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TETRACAINE HYDROCHLORIDE (UNII: 5NF5D4OPCI) (TETRACAINE - UNII:0619F35CGV)	TETRACAINE HYDROCHLORIDE	5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BORIC ACID (UNII: R57ZHV85D4)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
CHLOROBUTANOL (UNII: HM4YQM8WRC)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70518-2224-0	1 in 1 CARTON	07/18/2019	
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
unapproved drug other		07/18/2019	

Labeler - REMEDYREPACK INC. (829572556)

Revised: 7/2019 REMEDYREPACK INC.