TETRACAINE HYDROCHLORIDE- tetracaine hydrochloride solution
Somerset Therapeutics, LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use TETRACAINE HYDROCHLORIDE OPHTHALMIC SOLUTION safely and effectively. See full prescribing information for TETRACAINE HYDROCHLORIDE OPHTHALMIC SOLUTION
TETRACAINE HYDROCHLORIDE for topical ophthalmic use.
Initial U.S. Approval: 1965

RECENT MAJOR CHANGES

Warnings and Precautions (5.4) 2/2022

INDICATIONS AND USAGE

Tetracaine hydrochloride ophthalmic solution, 0.5%, is an ester local anesthetic indicated for procedures requiring a rapid and short-acting topical ophthalmic anesthetic. (1) (1)

DOSAGE AND ADMINISTRATION

One drop topically in the eye(s) as needed. (2) (2)

DOSAGE FORMS AND STRENGTHS

Ophthalmic solution containing 0.5% tetracaine hydrochloride. (3) (3)

CONTRAINDICATIONS

Tetracaine hydrochloride ophthalmic solution, 0.5% should not be used in patients with a history of hypersensitivity to any component of this preparation. (4) (4)

WARNINGS AND PRECAUTIONS

Do not use intracamerally since use may damage corneal endothelial cells. (5.1) (5)

- Prolonged use or abuse may lead to corneal epithelial toxicity and may manifest as epithelial defects which may progress to permanent corneal damage. (5.2)
- Patients should not touch the eye for at least 10-20 minutes after using anesthetic as accidental injuries can occur due to insensitivity of the eye. (5.3)
- For Administration by Healthcare Provider : Tetracaine Hydrochloride Ophthalmic Solution, USP 0.5% is not intended for patient self- administration. (5.4)

ADVERSE REACTIONS

Ocular adverse events: transient stinging, burning, conjunctival redness, eye irritation, eye pain, ocular discomfort. (6) (6)
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. (6)
See 17 for PATIENT COUNSELING INFORMATION.

Revised: 12/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Tetracaine hydrochloride ophthalmic solution, 0.5% is indicated for procedures requiring a rapid and short-acting topical ophthalmic anesthetic.

2 DOSAGE AND ADMINISTRATION

One drop topically in the eye(s) as needed.

3 DOSAGE FORMS AND STRENGTHS

Tetracaine hydrochloride ophthalmic solution, USP 0.5% is a clear, colorless, ophthalmic solution containing 0.5% w/v tetracaine hydrochloride equivalent to tetracaine 0.44% w/v.

4 CONTRAINDICATIONS

Tetracaine hydrochloride ophthalmic solution, 0.5% should not be used in patients with a history of hypersensitivity to any component of this preparation.

5 WARNINGS AND PRECAUTIONS

5.1 Corneal Injury with Intracameral Use

Not for injection or intraocular use. Do not use intracamerally because use of tetracaine hydrochloride ophthalmic solution, 0.5% may lead to damage of the corneal endothelial cells.

5.2 Corneal Toxicity

Prolonged use or abuse may lead to corneal epithelial toxicity and may manifest as epithelial defects which may progress to permanent corneal damage.

5.3 Corneal Injury Due to Insensitivity

Patients should not touch the eye for at least 10-20 minutes after using anesthetic as accidental injuries can occur due to insensitivity of the eye.

5.4 For Administration by Healthcare Provider

Tetracaine hydrochloride ophthalmic solution, 0.5% is indicated for administration under the direct supervision of a healthcare provider. Tetracaine Hydrochloride Ophthalmic Solution, 0.5% is not intended for patient self-administration *[see Warnings and Precautions (5.2)]*.

6 ADVERSE REACTIONS

The following serious ocular adverse reactions are described elsewhere in the labeling:

- Corneal Injury with Intracameral Use *[see Warnings and Precautions (5.1)]*
- Corneal Toxicity *[see Warnings and Precautions (5.2)]*
- Corneal Injury Due to Insensitivity [*see Warnings and Precautions (* 5.3)]

The following adverse reactions have been identified following use of tetracaine hydrochloride ophthalmic solution, 0.5%. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Ocular Adverse Reactions

Transient stinging, burning, and conjunctival redness, eye irritation, eye pain, ocular discomfort.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled studies with tetracaine hydrochloride ophthalmic solution, 0.5% in pregnant women. Animal developmental and reproductive toxicity studies with tetracaine hydrochloride have not been reported in the published literature.

8.2 Lactation

Risk Summary

There are no data to assess whether tetracaine hydrochloride ophthalmic solution, 0.5% is excreted in human milk or to assess its effects on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for tetracaine hydrochloride ophthalmic solution, 0.5% and any potential adverse effects on the breastfed child from tetracaine hydrochloride ophthalmic solution, 0.5%.

8.3 Females and Males of Reproductive Potential

No human data on the effect of tetracaine hydrochloride ophthalmic solution, 0.5% on fertility are available.

8.4 Pediatric Use

Safety of tetracaine hydrochloride ophthalmic solution, 0.5% in the pediatric population has been demonstrated in clinical trials. Efficacy of tetracaine hydrochloride ophthalmic solution, 0.5% for use in pediatric patients has been extrapolated from adequate and well controlled clinical trials in the adult population.

8.5 Geriatric Use

No overall differences in safety or effectiveness of tetracaine hydrochloride ophthalmic solution, 0.5% have been observed between elderly and younger patients.

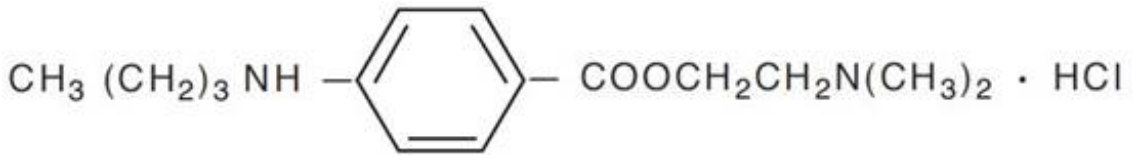
10 OVERDOSAGE

Prolonged use of a topical ocular anesthetic including tetracaine hydrochloride ophthalmic solution, 0.5% may produce permanent corneal opacification and ulceration with accompanying visual loss.

11 DESCRIPTION

Tetracaine hydrochloride ophthalmic solution, USP 0.5% is a sterile, clear, colorless, topical local anesthetic for ophthalmic use only containing tetracaine hydrochloride as the active pharmaceutical ingredient.

Tetracaine hydrochloride is chemically designated as benzoic acid, 4-(butylamino)-, 2-(dimethylamino) ethyl ester, monohydrochloride. Its chemical formula is $C_{15}H_{24}N_2O_2 \bullet HCl$ and it is represented by the chemical structure:



Tetracaine hydrochloride is a white crystalline powder with a molecular weight of 300.82

Active ingredient: tetracaine hydrochloride 0.5% w/v (equivalent to 0.44% w/v

tetracaine)

Preservative: chlorobutanol 0.4%

Inactive ingredients: boric acid, potassium chloride, edetate disodium dihydrate, water for injection. Sodium hydroxide and/or hydrochloric acid may be added to adjust pH (3.7 – 6.0).

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Tetracaine blocks sodium ion channels required for the initiation and conduction of neuronal impulses thereby affecting local anesthesia.

12.3 Pharmacokinetics

The systemic exposure to tetracaine following topical ocular administration of tetracaine hydrochloride ophthalmic solution, 0.5% has not been studied. Tetracaine hydrochloride is metabolized by plasma pseudocholinesterases and nonspecific esterases in ocular tissues.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies to assess the genotoxicity of tetracaine hydrochloride have not been reported in the published literature. Long-term animal studies have not been conducted to evaluate the carcinogenic potential of tetracaine hydrochloride. Animal studies to assess the effects of tetracaine hydrochloride on fertility have not been reported in the published literature.

14 CLINICAL STUDIES

Topical administration of tetracaine hydrochloride ophthalmic solution, 0.5% results in localized temporary anesthesia. The maximum effect is achieved within 10–20 seconds after instillation, with efficacy lasting 10–20 minutes. Duration of effect can be extended with repeated dosing *[see Warnings and Precautions (5.2) and Overdosage (10)]*.

16 HOW SUPPLIED/STORAGE AND HANDLING

Tetracaine hydrochloride ophthalmic solution, USP 0.5% is supplied as a sterile, aqueous, topical ophthalmic solution in a white LDPE bottle, plugged with white LDPE nozzle and capped with white HDPE cap in the following sizes:

NDC 70069-596-01, 5 mL fill in 5 mL Bottle

NDC 70069-597-01, 15 mL fill in 15 mL Bottle

After opening, this product can be used until the expiration date stamped on the bottle.

Storage: Store at 15° to 25°C (59° to 77°F). Protect from light. Do not use if solution

contains crystals, cloudy, or discolored.

17 PATIENT COUNSELING INFORMATION

Eye Care Precaution

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

Advise patients that, due to the effect of the anesthetic, their eyes will be insensitive for up to 20 minutes and that care should be taken to avoid accidental injuries.

SPL UNCLASSIFIED

Manufactured for:

Somerset Therapeutics, LLC

Somerset, NJ 08873

Made in India

Code No.: KR/DRUGS/KTK/28/289/97

ST-TEC/P/00

1200992

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Container Label

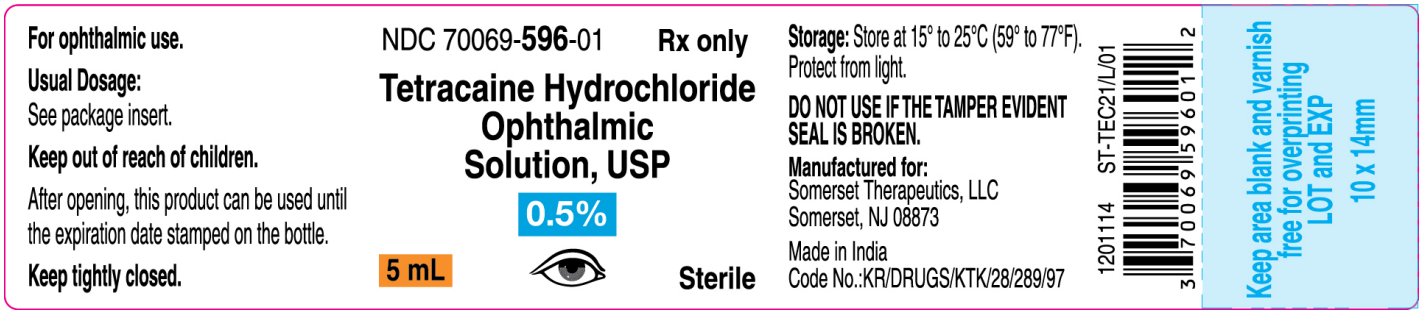
NDC 70069-596-01

Tetracaine Hydrochloride Ophthalmic Solution USP, 0.5%

Sterile

Rx only

5 mL



Carton Label

NDC 70069-596-01

Tetracaine Hydrochloride Ophthalmic Solution USP, 0.5%

Sterile

Rx only

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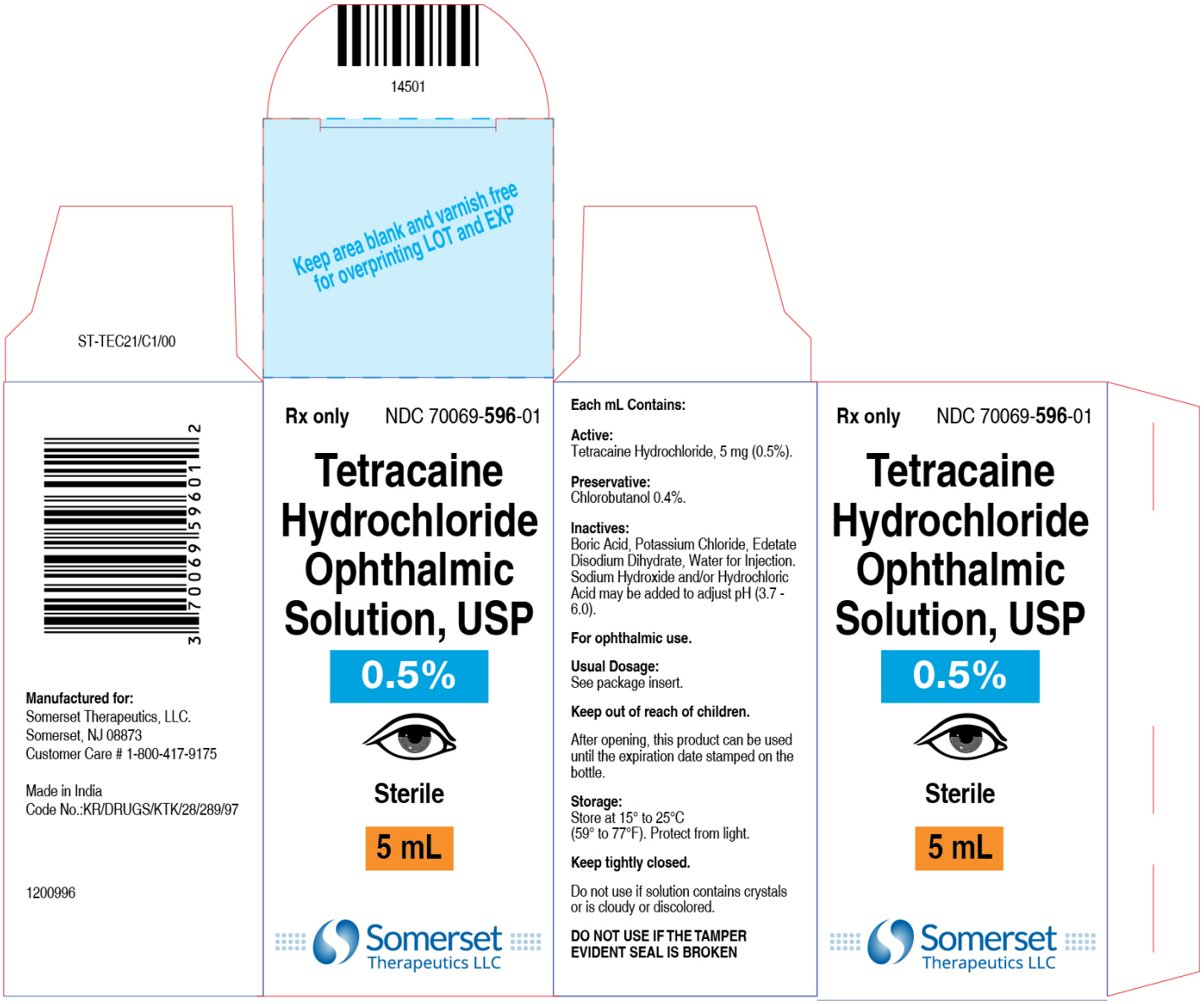


Container Label

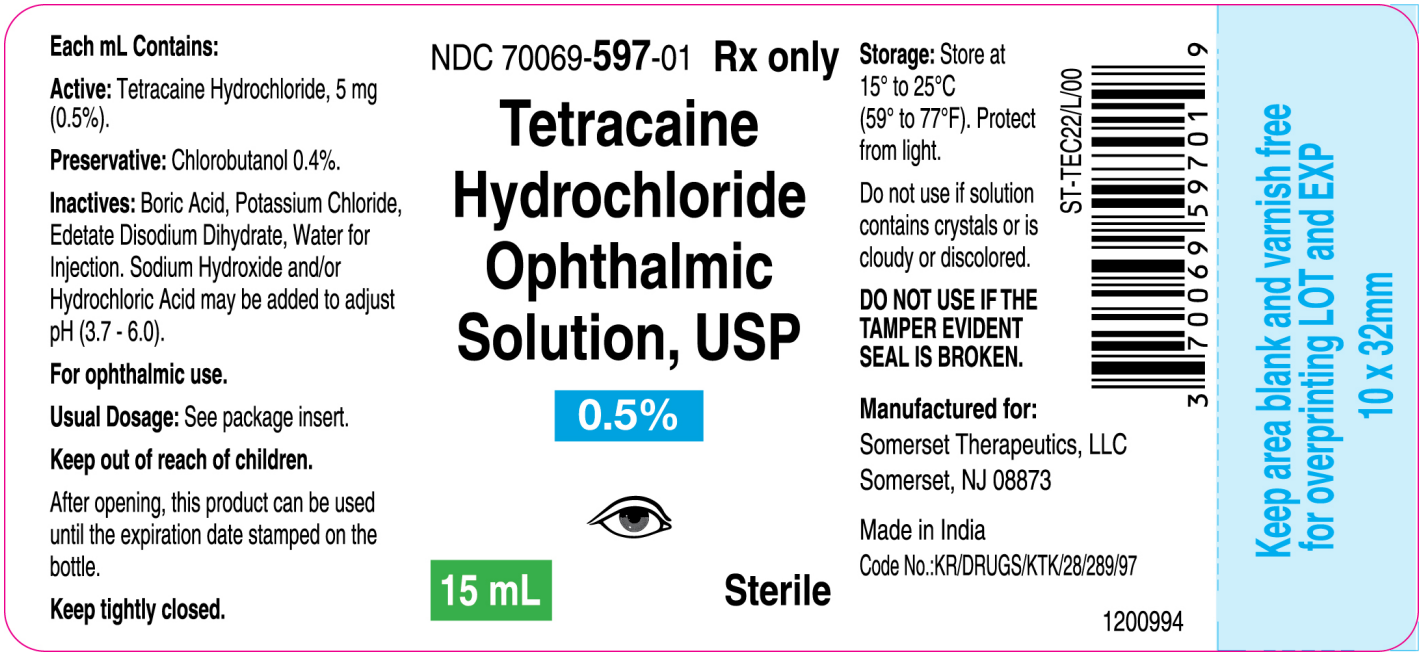
NDC 70069-597-01

Tetracaine Hydrochloride Ophthalmic Solution USP, 0.5%

Sterile

Rx only

15 mL



Carton Label

NDC 70069-597-01

Tetracaine Hydrochloride Ophthalmic Solution USP, 0.5%

Sterile

Rx only

15 mL

TETRACAINE HYDROCHLORIDE

tetracaine hydrochloride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70069-596
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**
CHLOROBUTANOL (UNII: HM4YQM8WRC)	
BORIC ACID (UNII: R57ZHV85D4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70069-596-01	1 in 1 CARTON	12/23/2024	
1		5 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	ANDA217227	12/23/2024	

TETRACAINE HYDROCHLORIDE

tetracaine hydrochloride solution

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ANDA	ANDA217227	12/23/2024	

Labeler - Somerset Therapeutics, LLC (079947873)

Registrant - Somerset Therapeutics, LLC (079947873)

Establishment

Name	Address	ID/FEI	Business Operations
Somerset Therapeutics Private Limited		677236695	ANALYSIS(70069-596, 70069-597) , LABEL(70069-596, 70069-597) , PACK(70069-596, 70069-597) , MANUFACTURE(70069-596, 70069-597)

Revised: 12/2024 Somerset Therapeutics, LLC