

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

210821Orig1s000

LABELING

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Tetracaine Hydrochloride Ophthalmic Solution USP, 0.5% safely and effectively. See full prescribing information for Tetracaine Hydrochloride Ophthalmic Solution USP, 0.5%.

Tetracaine Hydrochloride Ophthalmic Solution USP, 0.5%, for topical ophthalmic use

Initial U.S. Approval: 1965

INDICATIONS AND USAGE

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

DOSAGE AND ADMINISTRATION

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

DOSAGE FORMS AND STRENGTHS

Sterile, preserved, ophthalmic solution containing 0.5% tetracaine hydrochloride. (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)

WARNINGS AND PRECAUTIONS

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

ADVERSE REACTIONS

Ocular adverse events: transient stinging, burning, conjunctival redness, eye irritation, eye pain, ocular discomfort. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Bausch & Lomb, a Division of Valeant Pharmaceuticals North America LLC, at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 03/2019

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Tetracaine Hydrochloride Ophthalmic Solution USP, 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, USP, 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 USP, 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.

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 USP, 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 USP, 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 USP, 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 USP, 0.5% and any potential adverse effects on the breastfed child from Tetracaine Hydrochloride Ophthalmic Solution USP, 0.5%.

8.3 Females and Males of Reproductive Potential

No human data on the effect of Tetracaine Hydrochloride Ophthalmic Solution USP, 0.5% on fertility are available.

8.4 Pediatric Use

Safety of Tetracaine Hydrochloride Ophthalmic Solution USP, 0.5% in the pediatric population has been demonstrated in clinical trials. Efficacy of Tetracaine Hydrochloride Ophthalmic Solution USP, 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 USP, 0.5% have been observed between elderly and younger patients.

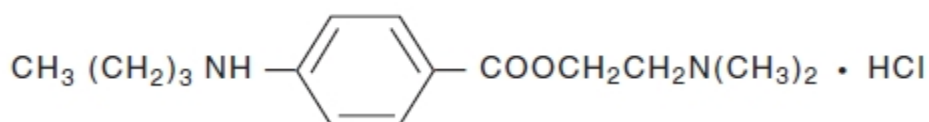
10 OVERDOSAGE

Prolonged use of a topical ocular anesthetic including Tetracaine Hydrochloride Ophthalmic Solution USP, 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 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 $C_{15}H_{24}N_2O_2 \cdot HCl$ and it is represented by the chemical structure:



Tetracaine hydrochloride is a fine, white, crystalline, odorless 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, water for injection USP. 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 USP, 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 USP, 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 with a fill volume of 15 mL in a 15 mL low-density polyethylene plastic dropper bottle with a low-density polyethylene dropper tip and white polypropylene cap.

NDC 42702-170-15

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

Storage: Store at 15°C to 25°C (59°F 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.

Manufactured for:
Paragon BioTeck, Inc.
4640 SW Macadam Ave, Ste 80
Portland, OR 97239

Manufactured and Distributed by:
Bausch & Lomb
8500 Hidden River Pkwy
Tampa, FL 33637
Revised: March 2019

Container Label:

Each mL Contains:

Active: Tetracaine Hydrochloride,
5 mg (0.5%).

Preservative:
Chlorobutanol 0.4%.

Inactives: Boric Acid, Potassium
Chloride, Edetate Disodium,
Water for injection. Sodium
Hydroxide and/or Hydrochloric
Acid may be added to adjust
pH (3.7-6.0).

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NDC 42702-170-15



**Tetracaine
Hydrochloride
Solution, USP
0.5% (Sterile)**

FOR OPHTHALMIC USE.

Usual Dosage:
See package insert.

KEEP OUT OF REACH
OF CHILDREN.

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

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

KEEP TIGHTLY CLOSED.

Do not use if solution
contains crystals or is
cloudy or discolored.

**DO NOT USE IF IMPRINTED
NECKBAND IS NOT INTACT.**



(01)00342702170156

Rx Only **15 mL**

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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