

**TETRACAINE HYDROCHLORIDE- tetracaine hydrochloride solution/ drops**  
**Paragon BioTeck, Inc.**

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**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](http://www.fda.gov/medwatch).**

**See 17 for PATIENT COUNSELING INFORMATION.**

**Revised: 3/2019**

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

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**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.

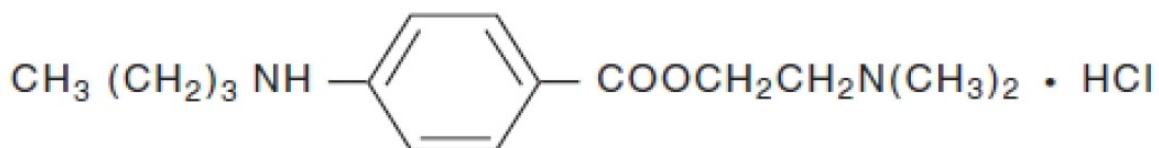
## 10 OVERDOSAGE

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

**PACKAGE/LABEL PRINCIPAL DISPLAY PANEL- Carton 15 mL**

NDC 42702-170-15

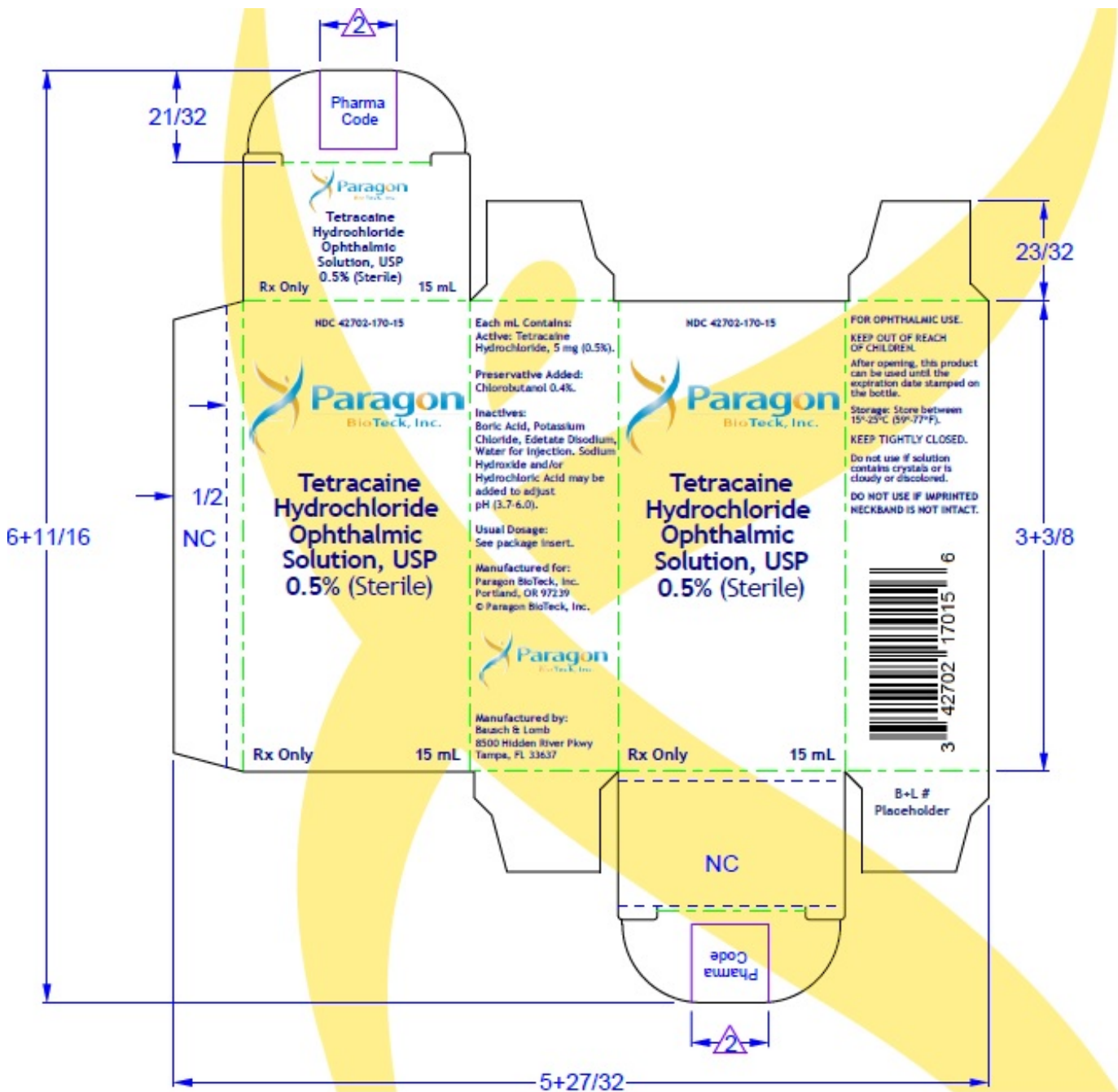
**Paragon  
BioTeck, Inc.**

**Tetracaine  
Hydrochloride**

**Ophthalmic  
Solution, USP  
0.5% (Sterile)**

**Rx Only**

**15 mL**



# TETRACAINE HYDROCHLORIDE

tetracaine hydrochloride solution/ drops

## Product Information

|                                |                         |                           |               |
|--------------------------------|-------------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:42702-170 |
| <b>Route of Administration</b> | OPHTHALMIC              |                           |               |

## Active Ingredient/Active Moiety

| <b>Ingredient Name</b>   | <b>Basis of Strength</b>    | <b>Strength</b> |
|--|-----------------------------|-----------------|
| TETRACAINE HYDROCHLORIDE (UNII: 5NF5D4OPCI) (TETRACAINE - UNII:0619F35CGV) | TETRACAINE<br>HYDROCHLORIDE | 5 mg<br>in 1 mL |

## Inactive Ingredients

| <b>Ingredient Name</b>                | <b>Strength</b> |
|---------------------------------------|-----------------|
| CHLOROBUTANOL (UNII: HM4YQM8WRC)      |                 |
| BORIC ACID (UNII: R57ZHV85D4)         |                 |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) |                 |
| EDETATE DISODIUM (UNII: 7FLD91C86K)   |                 |
| WATER (UNII: 059QF0K00R)              |                 |
| SODIUM HYDROXIDE (UNII: 55X04QC32I)   |                 |
| HYDROCHLORIC ACID (UNII: QTT17582CB)  |                 |

## Packaging

| # | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:42702-170-15 | 1 in 1 CARTON  | 03/12/2019           |                    |
| 1 |                  | 15 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| NDA                       | NDA210821                                       | 03/12/2019                  |                           |

**Labeler** - Paragon BioTeck, Inc. (078279037)

## Establishment

| <b>Name</b>                | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|----------------------------|----------------|---------------|----------------------------|
| Bausch & Lomb Incorporated |                | 079587625     | MANUFACTURE(42702-170)     |

Revised: 3/2019

Paragon BioTeck, Inc.