**HIGHLIGHTS OF PRESCRIBING INFORMATION**

**These highlights do not include all the information needed to use Tetracaine Hydrochloride Ophthalmic Solution 0.5% STERI-UNIT® safely and effectively. See full prescribing information for Tetracaine Hydrochloride Ophthalmic Solution.**

**Tetracaine Hydrochloride Ophthalmic Solution 0.5% STERI-UNIT®, topical ophthalmic**
**Initial U.S. Approval: 1965**

**----------INDICATIONS AND USAGE ----------**

Tetracaine Hydrochloride Ophthalmic Solution 0.5%, an ester local anesthetic, is 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. Discard unused portion. (2.1)

**----------DOSAGE FORMS AND STRENGTHS ----------**

Sterile ophthalmic solution containing 0.5% tetracaine hydrochloride (3)

**----------CONTRAINDICATIONS----------**

None (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: stinging, burning, conjunctival redness

**To report SUSPECTED ADVERSE REACTIONS, contact Alcon Laboratories, Inc., at 1-800-757-9195 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

**----------PATIENT COUNSELING INFORMATION----------**

Advise patients that their eyes will be insensitive and that care should be taken to avoid accidental injuries.

**Revised: 02/2016**

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**FULL PRESCRIBING INFORMATION: CONTENTS***



*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 0.5% is indicated for procedures requiring a rapid and short-acting topical ophthalmic anesthetic.

## 2 DOSAGE AND ADMINISTRATION

### 2.1 Topical Administration

One drop topically in the eye as needed. Discard unused portion.

### 2.2 Sterile Field Administration

Open package using standard aseptic technique. The DROP-TAINER® dispenser may then be allowed to fall upon a sterile surface. The entire outer surface of the DROP-TAINER® dispenser and its contents are sterile.

## 3 DOSAGE FORMS AND STRENGTHS

Sterile ophthalmic solution containing 0.5% w/v tetracaine hydrochloride equivalent to tetracaine 0.44% w/v.

## 4 CONTRAINDICATIONS

None.

## 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.

## 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 reliable 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.
**12**

### 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% or from the underlying maternal condition.

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

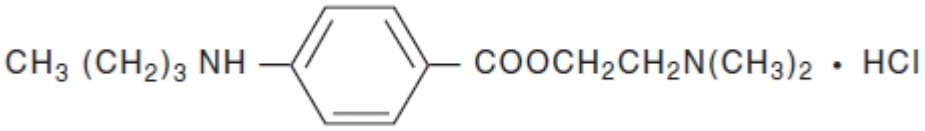
### 8.5 Geriatric Use
No overall differences in safety or effectiveness of tetracaine hydrochloride ophthalmic solution have been observed between elderly and younger patients.

## 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. Symptoms related to systemic toxicity consist mainly of effects on the neurologic and cardiovascular systems.

## 11 DESCRIPTION

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




Tetracaine hydrochloride is a fine, white, crystalline, odorless powder and has a molecular weight of 300.82. Tetracaine Hydrochloride Ophthalmic Solution 0.5% has a pH of 3.7 to 5.5.

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

**Inactive ingredients:** sodium chloride, sodium acetate trihydrate, acetic acid (to adjust pH approximately 4.5), Water for Injection, USP

## 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 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 Corneal toxicity (5.2) and Overdosage (10*)].

## 16 HOW SUPPLIED/STORAGE AND HANDLING

Tetracaine Hydrochloride Ophthalmic Solution 0.5% STERI-UNITS® is supplied as single patient use, 4 mL filled in 4-mL natural medium- or low-density polyethylene plastic DROP-TAINER® dispensers and natural low-density polyethylene tips with white polypropylene caps in a carton of 12. Each sterilized DROP-TAINER® dispenser is packaged in a clear PVC and Tyvek blister. This product does not contain a preservative, discard unused portion.

**NDC** 0065-0741-12
**Storage:** Store at 2°C to 25°C (36°F to 77°F). Protect from light. Do not use if solution contains crystals, cloudy, or discolored.

## 17 PATIENT COUNSELING INFORMATION

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

**ALCON®**
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