

### 1.6.3 Patient Information leaflet (PIL)



If a drop misses your eye, try again.

#### INTERACTIONS WITH OTHER MEDICATIONS

Aurocaine has hypersensitivity to p-amino benzoic acid or its derivatives.

#### PREGNANCY & LACTATION USE PRECAUTIONS

Safety for use during pregnancy has not been established. Use only when clearly needed and when potential benefits outweigh potential hazards to the fetus.

Safety for use during lactation has not been established. Use only when clearly needed and when potential benefits outweigh potential hazards to the infant.

#### ADVERSE REACTIONS

Prolonged use may diminish duration of anesthesia, retard wound healing and cause corneal epithelial erosions. Systemic toxicity is rare with topical ophthalmic application of local anesthetics. It usually occurs as CNS stimulation followed by CNS and cardiovascular depression. Local or systemic sensitivity occurs occasionally. At recommended concentration and dosage Proparacaine usually produces little or no initial irritation, stinging, burning, conjunctival redness, lacrimation or increased winking. However, some local irritation and stinging may occur several hours after instillation. Allergic contact dermatitis with drying and fissuring of the fingertips and softening and erosion of the corneal epithelium and conjunctival congestion and hemorrhage has been reported.

#### DOSAGE AND ADMINISTRATION

Aurocaine should be applied topically to the eye as directed by the physician.

#### SUPPLY

Aurocaine ophthalmic solution: 5 ml is supplied in sterile white opaque plastic container.

#### Storage condition

Store below 30°C

#### Manufacturer:

Aurolab

No.1, Sivagangai Main Road,  
Veerapanjan, Madurai - 625 020. (INDIA)  
Tel : 91-452-3096100  
Fax : 91-452-2446200  
Email : [sales@aurolab.com](mailto:sales@aurolab.com)  
Web : [www.aurolab.com](http://www.aurolab.com)

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### Instructions for use leaflet

## AUROCAINE™

(Proparacaine HCL ophthalmic solution USP 0.5% w/v)

#### DESCRIPTION

Aurocaine is clear, colorless solution and each ml contains 5 mg of Proparacaine HCL and Benzalkonium chloride 0.1 mg as preservative.

#### CLINICAL PHARMACOLOGY

Aurocaine stabilize the neuronal membrane so the neuron is less permeable to ions. This prevents the initiation and transmission of nerve impulses, thereby producing the local anesthetic action. Studies indicate that local anesthetics influence permeability of the nerve cell membrane by limiting sodium ion permeability by closing the pores through which the ions migrate in the lipid layer of the nerve cell membrane. This limitation prevents the fundamental change necessary for the generation of the action potential. It has a rapid onset of anesthesia beginning within 13 to 30 seconds following instillation; the duration of action is 15 to 20 minutes.

#### INDICATIONS

Corneal anesthesia of short duration (e.g. tonometry, gonioscopy, removal of corneal foreign bodies and suture); short corneal and conjunctival procedures; cataract surgery; conjunctival and corneal scraping for diagnostic purposes; paracentesis of the anterior chamber.

#### CONTRAINDICATIONS

Hypersensitivity to similar drugs (ester-type local anesthetics), para-aminobenzoic acid or its derivatives or to any other ingredient in these preparations; prolonged use, especially for self-medication.

#### WARNINGS

Not for injection. For topical ophthalmic use only. Do not touch the nozzle tip to any surface, since this may contaminate the solution.

#### PRECAUTIONS

Protection of the eye from irritating chemicals, foreign bodies and rubbing during the period of anesthesia is very important. Advise the patient to avoid touching the eye until anesthesia has worn off.

Use caution in patients with abnormal or reduced levels of plasma esterases. Use cautiously and sparingly in patients with known allergies, cardiac disease or hyperthyroidism.