1.6 Product Information

1.6.1 Summary of Product characteristics.
AUROCAINE (Proparacaine Hydrochloride Ophthalmic solution USP 0.5%w/v)

1. Name of the medicinal product
AUROCAINE.

2. Qualitative and quantitative composition
Each ml contains,

Proparacaine Hydrochloride	USP	0.5%w/v
Benzalkonium chloride	BP	0.01%w/v
Excipients	q.s	

3. Pharmaceutical form
Eye drops, solution.
Clear colorless sterile aqueous solution.

4. Clinical particulars
4.1 Therapeutic indications

Proparacaine hydrochloride ophthalmic solution is indicated for procedures in which a topical ophthalmic anesthetic is indicated; corneal anesthesia of short duration, e.g. tonometry, gonioscopy, removal of corneal foreign bodies and for short corneal and conjunctival procedures.

4.2 Posology and method of administration

Usual dosage: Removal of foreign bodies and sutures, and for tonometry: 1 to 2 drops (in single instillations) in each eye before operating. Short corneal and conjunctival procedures: 1 drop in each eye every 5 to 10 minutes for 5 to 7 doses.

4.3 Contraindications

Proparacaine hydrochloride ophthalmic solution is contraindicated in patients with known hypersensitivity to any of the ingredients of this preparation.

4.4 Special warnings and precautions for use

NOT FOR INJECTION INTO THE EYE - FOR TOPICAL OPHTHALMIC USE ONLY Prolonged use of a topical ocular anesthetic is not recommended. It may produce permanent corneal opacification with accompanying visual loss.

4.5 Interaction with other medicinal products and other forms of interaction

Not known.

4.6 Pregnancy and lactation

Animal reproduction studies have not been conducted with Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%. It is also not known whether proparacaine hydrochloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Proparacaine hydrochloride should be administered to a pregnant woman only if clearly needed.

Nursing Mothers It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when proparacaine hydrochloride is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

There is no specific requirement is required.

4.8 Undesirable effects/Adverse effects

Occasional temporary stinging, burning and conjunctival redness may occur with the use of proparacaine. A rare, severe, immediate-type, apparently hyperallergic corneal reaction characterized by acute, intense and diffuse epithelial keratitis, a gray, ground glass appearance, sloughing of large areas of necrotic epithelium, corneal filaments and sometimes iritis with descemetitis has been reported. Allergic contact dermatitis from proparacaine with drying and fissuring of the fingertips has been reported.

Pediatric Use
Safety and effectiveness of proparacaine hydrochloride ophthalmic solution in pediatric patients have been established. Use of proparacaine hydrochloride is supported by evidence from adequate and well-controlled studies in adults and children over the age of twelve, and safety information in neonates and other pediatric patients.

Geriatric Use No overall clinical differences in safety of effectiveness have been observed between the elderly and other adult patients.

4.9 Overdose
No information provided.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Clinical Pharmacology:
Proparacaine hydrochloride ophthalmic solution is a rapid acting local anesthetic suitable for ophthalmic use. The onset of anesthesia usually begins within 30 seconds and lasts a relatively short period of time. The main site of anesthetic action is the nerve cell membrane where proparacaine interferes with the large transient increase in the membrane permeability to sodium ions that is internally produced by a slight depolarization of the membrane. As the anesthetic action progressively develops in a nerve, the threshold for electrical stimulation gradually increases and the safety factor for conduction decreases; when this action is sufficiently well developed, block of conduction is produced. The exact mechanism whereby proparacaine and other local anesthetics influence the permeability of the cell membrane is unknown; however, several studies indicate that local anesthetics may limit

sodium ion permeability through the lipid layer of the nerve cell membrane. This limitation prevents the fundamental change necessary for the generation of the action potential.

Mechanism of action:
Reversibly blocks nerve conduction near the site of application
May limit sodium ion permeability through the lipid layer of the nerve cell membrane

5.2 Pharmacokinetic properties

Onset: 30 sec
Duration: 10-20 min

5.3 Preclinical safety data

Not known.

6. Pharmaceutical particulars
6.1 List of excipients

Benzalkonium chloride BP
Purified water BP

6.2 Incompatibilities
None known.

6.3 Shelf life
12months unopened.
Discard 28 days after first opening.

6.4 Special precautions for storage
Do not store above 30°C.

6.5 Nature and contents of container
Packed in 10ml Low density polyethylene container with HDPE cap and Nozzle. Such 10ml is packed in a monocarton with package insert.

6.6 Special precautions for disposal and other handling
There is no special requirement for disposal.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder
Aurolab, No.1, Sivagangai Main road, Veerapanjan, Madurai - 625020, India**.**

8. Marketing authorisation number(s)
TN 00002387

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9. Date of renewal of the authorisation
11.07.2022

10. Date of revision of the text
Not Applicable