Alcaine®
(proparacaine hydrochloride ophthalmic solution, USP) 0.5%

DESCRIPTION: ALCAINE® (proparacaine hydrochloride ophthalmic solution, USP) 0.5% is a topical local anesthetic for ophthalmic use. The active ingredient is represented by the structural formula:

Established name: Proparacaine Hydrochloride
Chemical name: Benzoic acid, 3-amino-4-propoxy-2-diethylaminoethyl ester, monohydrochloride.

Molecular Weight: 330.85

Each mL contains: Active: proparacaine hydrochloride 5 mg 0.5%. Preservative: benzalkonium chloride (0.01%). Inactives: glycerin and purified water. The pH may be adjusted with hydrochloric acid and/or sodium hydroxide.

CLINICAL PHARMACOLOGY: ALCAINE® ophthalmic solution is a rapidly-acting topical anesthetic, with induced anesthesia lasting approximately 10-20 minutes.

INDICATIONS AND USAGE: ALCAINE® 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.

CONTRAINDICATIONS: ALCAINE® ophthalmic solution should be considered contraindicated in patients with known hypersensitivity to any of the ingredients of this preparation.

WARNINGS: NOT FOR INJECTION – 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.

PRECAUTIONS: Carcinogenesis, Mutagenesis, Impairment of Fertility. Long-term studies in animals have not been performed to evaluate carcinogenic potential, mutagenicity, or possible impairment of fertility in males or females.

Pregnancy: Pregnancy Category C: Animal reproduction studies have not been conducted with ALCAINE® (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.

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 or effectiveness have been observed between the elderly and other adult patients.

ADVERSE REACTIONS: Occasional temporary stinging, burning and conjunctival redness may occur with the use of proparacaine. A rare, severe, immediate-type, apparently hypersalergic 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.