

PRODUCT INFORMATION

ALCAINE[®]

Proparacaine Hydrochloride Sterile Ophthalmic Solution, USP

5 mg/mL

Topical Anesthetic

Novartis Pharmaceuticals Canada Inc.
385 Bouchard Blvd.,
Dorval, Quebec
H9S 1A9

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ALCAINE is a registered trademark.

DESCRIPTION: ALCAINE[®] (proparacaine hydrochloride) ophthalmic solution is a topical anesthetic prepared as a sterile aqueous ophthalmic solution. Each mL contains:

- Medicinal ingredient: Proparacaine Hydrochloride 0.5% (5 mg)
- Preservative: Benzalkonium Chloride 0.01%
- Nonmedicinal ingredients: Glycerin, Hydrochloric Acid and/or Sodium Hydroxide (to adjust pH), Purified water

CLINICAL PHARMACOLOGY: ALCAINE (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 by which 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.

INDICATIONS AND USAGE: ALCAINE (proparacaine hydrochloride) ophthalmic solution is indicated for use as a topical anesthesia:

- for ophthalmic procedures such as measurement of intraocular pressure (tonometry), removal of foreign bodies and sutures from cornea, conjunctive scraping in diagnosis and gonioscopic examination
- prior to surgical operations such as cataract extraction

CONTRAINDICATIONS

- ALCAINE (proparacaine hydrochloride) ophthalmic solution is contraindicated in patients who are hypersensitive to proparacaine hydrochloride or to any ingredient in the formulation or component of the container.
- ALCAINE solution should never be prescribed for the patient's own use.

WARNINGS

- ALCAINE (proparacaine hydrochloride) is for topical ophthalmic use only by health care professionals.
- Do not touch dropper tip to any surface as this may contaminate the solution.
- Prolonged use or abuse of topical ocular anesthetics, including ALCAINE, may lead to corneal epithelial toxicity and may manifest as epithelial defects, which may progress to permanent corneal damage, such as corneal opacification with accompanying loss of vision.

PRECAUTIONS:

General. Proparacaine hydrochloride should be used with caution in patients with known allergies, cardiac diseases, or hyperthyroidism.

Prolonged use of proparacaine hydrochloride may diminish the duration of anesthesia.

The long-term toxicity of proparacaine is not known; prolonged use may delay wound healing (see WARNINGS).

Ophthalmologic. ALCaine solution contains benzalkonium chloride, which may cause eye irritation and is known to discolour soft contact lenses.

Protection of the eye from irritating chemicals, foreign bodies and rubbing during the period of anesthesia is very important. Patients should be advised to avoid touching the eye until the anesthesia has worn off. Additionally, contact lens wear is not recommended until the anesthetic has worn-off.

Skin. Proparacaine may cause allergic contact dermatitis. Avoid contact of ALCaine (proparacaine hydrochloride) ophthalmic solution with the skin.

Carcinogenesis and Mutagenesis. Long-term studies in animals have not been performed to evaluate carcinogenic potential or mutagenicity.

Fertility. Long term studies in animals have not been performed to evaluate the effect of proparacaine on fertility in males or females.

Pregnant Women. Animal reproduction studies have not been conducted with ALCaine solution. It is not known whether proparacaine hydrochloride can cause fetal harm when administered to a pregnant woman. ALCaine solution is not recommended during pregnancy.

Nursing Women. It is not known whether ALCaine solution is excreted in human milk; however, a risk to the child cannot be excluded. Because many drugs are excreted in human milk, caution should be exercised when proparacaine hydrochloride is administered to a nursing woman.

Pediatrics. Controlled clinical studies have not been performed with ALCaine solution to establish safety and effectiveness in children. Proparacaine hydrochloride may be used as a topical ophthalmic anesthetic agent in children when benefit outweighs potential risks.

Ability to Drive and Use Machinery. Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs after administration, the patient should be advised to wait until vision clears before driving or using machinery.

ADVERSE REACTIONS:

Immune system disorders. Allergic contact dermatitis with drying and fissuring of the fingertips; hypersensitivity.

Nervous system disorders. Syncope.

Eye disorders. Eye irritation, stinging, burning, eye pain or eye swelling; ocular discomfort; ocular hyperaemia; conjunctival redness; increased lacrimation; increased winking; corneal opacity; keratitis; blurred vision; photophobia.

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.

Pupillary dilatation or cycloplegic effects have rarely been observed with proparacaine hydrochloride.

Softening and erosion of the corneal epithelium and conjunctival congestion and hemorrhage have been reported.

Misuse (e.g., uncontrolled use) or abuse of the product may lead to ocular lesions due to the toxic effects of the anesthetic to the corneal epithelium (see WARNINGS).

DRUG INTERACTIONS: No interaction studies have been performed; however, no clinically relevant interactions are expected.

DOSAGE AND ADMINISTRATION:

Deep anesthesia as in cataract extraction:

Instill 1 drop every 5 to 10 minutes for 5 to 7 doses.

Removal of sutures:

Instill 1 or 2 drops 2 or 3 minutes before removal of stitches.

Removal of foreign bodies:

Instill 1 or 2 drops prior to operating.

Tonometry:

Instill 1 or 2 drops immediately before measurement.

OVERDOSAGE:

In the event of overdose or accidental ingestion, systemic effects may manifest as central nervous system stimulation (which may include nervousness, tremors or convulsions) followed by central nervous system (CNS) and cardiovascular depression. CNS depression may result in loss of consciousness and respiratory depression.

For management of a suspected drug overdose, contact your regional Poison Control

HOW SUPPLIED: ALCAINE (proparacaine hydrochloride) ophthalmic solution is supplied in 15 mL DROP-TAINER^{*} dispensers.

STORAGE: Store at 2°C - 8°C. Keep refrigerated. Do not use if the solution is darker than a pale yellow.

CONSUMER INFORMATION

ALCAINE®

Proparacaine Hydrochloride Ophthalmic Solution, USP

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ALCAINE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ALCAINE is a local anesthetic used by your doctor during certain types of eye procedures and before eye surgery.

What it does:

ALCAINE temporarily numbs or blocks the sensation in your eye(s).

When it should not be used:

- ALCAINE should not be given to you if you are allergic to proparacaine hydrochloride or any of the other ingredients in ALCAINE.
- ALCAINE should only be put into your eye(s) by a healthcare professional and should not be given to you to use.

What the medicinal ingredient is:

Proparacaine hydrochloride

What the nonmedicinal ingredients are:

Preservative: benzalkonium chloride

Others: glycerin, hydrochloric acid and/or sodium hydroxide (to adjust pH), purified water.

What dosage forms it comes in:

ALCAINE is available as an eye drop solution.

WARNINGS AND PRECAUTIONS

BEFORE you are given ALCAINE tell your doctor if you:

- Have allergies.
- Have heart disease.
- Have an overactive thyroid (*hyperthyroidism*).
- Are pregnant.
- Are breastfeeding.
- Have received ALCAINE or similar products before and how often.

After you are given ALCAINE:

- Repeated use or abuse of this product may lead to permanent corneal disorders/eye damage, including loss of vision.
- Avoid touching and rubbing your eyes.
- Protect your eyes from irritating chemicals.
- Due to the effect of the anesthetic, your eyes will be numb and care should be taken to avoid accidental injuries to your eyes. Do not touch or rub the eye and take precautions to protect it from everyday contaminants

(such as dust, dirt, etc).

- Wear contact lenses only after sensation returns to your eye(s).
- Do not drive or use machines until your vision has cleared and is not blurry.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor about all the medicines you are taking, recently took or are planning to take, including those without a prescription.

PROPER USE OF THIS MEDICATION

ALCAINE should only be put into your eye(s) by a healthcare professional and should not be given to you to use.

Usual dose:

Your doctor will decide the dose you need based on the type of eye procedure or surgery you are having.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Known side effects in the eye include:

- Irritated, burning or stinging eyes
- Eye pain
- Eye swelling
- Eye redness
- Blurred vision
- Sensitivity to light
- Increased tearing and/or winking
- Dilated pupils
- Eye inflammation including the coloured part of the eye
- Scratch in the eye surface with or without softening
- Clouding of the eye surface
- Shedding of dead eye surface cells

Permanent corneal disorders/eye damage, including loss of vision, can occur with long term use or abuse of ALCAINE.

Known side effects in the rest of the body include: drying or splitting of the skin on your fingertips from repeated contact with ALCAINE and fainting.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Tell your doctor if you experience any of the following side effects:

- Allergic reaction (signs include shortness of breath, swelling of the face, lips or tongue, rash or hives).
- Nervousness, shaking (*tremors*) or seizures (*convulsions*).
- Loss of consciousness.
- Difficulty breathing.

This is not a complete list of side effects. Tell your doctor or pharmacist if you experience any unexpected side effects.

HOW TO STORE IT

ALCAINE is stored in the refrigerator between 2°C and 8°C.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect[™] Canada Web site at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Information, prepared for health professionals can be found at:
www.novartis.ca
or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at: 1-800- 363-8883.

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