

## PRESCRIBING INFORMATION

### **ODAN- PROPARACAINE**

Proparacaine Hydrochloride Ophthalmic Solution, USP  
5 mg/mL

Topical Anesthetic

ODAN LABORATORIES LTD.  
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 **ODAN**  
[www.odanlab.com](http://www.odanlab.com)

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Proparacaine Hydrochloride Ophthalmic Solution, USP  
5 mg/mL

#### **DESCRIPTION**

ODAN-PROPACCAINE (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**

ODAN-PROPACCAINE (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**

ODAN-PROPACCAINE (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**

ODAN-PROPACCAINE (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. ODAN-PROPACCAINE solution should never be prescribed for the patient's own use.

#### **WARNINGS**

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 of a topical ocular anesthetic 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 cautiously and sparingly 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 unknown; prolonged use may possibly delay wound healing. Although exceedingly rare with ophthalmic application of local anesthetics, systemic effects may manifest as central nervous system stimulation (which may include nervousness, tremors or convulsions) followed by depression, which may result in loss of consciousness and respiratory depression. Treatment of systemic effects should be symptomatic and supportive. 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. Tonometers soaked in sterilizing or detergent solutions should be thoroughly rinsed with sterile distilled water prior to use. Proparacaine may cause allergic contact dermatitis.

Avoid contact of ODAN-PROPARACAINE (proparacaine hydrochloride) ophthalmic solution with the skin. ODAN-PROPARACAINE solution contains benzalkonium chloride, which may cause eye irritation and is known to discolour soft contact lenses. Patients should be advised to avoid wearing contact lenses until the anesthetic has worn-off.

**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 ODAN-PROPARACAINE solution. It is not known whether proparacaine hydrochloride can cause fetal harm when administered to a pregnant woman. ODAN-PROPARACAINE solution is not recommended during pregnancy and should be administered to a pregnant woman only if clearly needed.

**Nursing Women:** It is not known whether ODAN-PROPARACAINE 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 ODAN-PROPARACAINE solution to establish safety and effectiveness in children. Proparacaine hydrochloride may be 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:** Irritation, stinging, burning, pain or swelling; ocular discomfort; ocular hyperaemia; conjunctival redness; lacrimation; increased winking; cornea erosion, including a gray, ground-glass appearance; corneal opacity; epithelial keratitis; sloughing of large areas of necrotic epithelium; corneal filaments; blurry vision; photophobia; iritis with descemetitis. 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.

## **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.

## **HOW SUPPLIED**

ODAN-PROPARACAINE (proparacaine hydrochloride) ophthalmic solution is supplied in 15 mL plastic dropper container.

## **STORAGE**

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

**CONSUMER INFORMATION**

**ODAN-PROPARACAINE**

**Proparacaine Hydrochloride Ophthalmic Solution, USP**

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

**ABOUT THIS MEDICATION**

**What the medication is used for:**

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

**What it does:**

ODAN-PROPARACAINE temporarily numbs or blocks the sensation in your eye(s).

**When it should not be used:**

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

**What the medicinal ingredient is:**

Proparacaine hydrochloride

**What the important 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:**

ODAN-PROPARACAINE is available as an eye drop solution.

**WARNINGS AND PRECAUTIONS**

**BEFORE you are given ODAN-PROPARACAINE tell your doctor if you:**

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

**After you are given ODAN-PROPARACAINE:**

- Avoid touching and rubbing your eyes.
- Protect your eyes from irritating chemicals.
- Wear contact lenses only after you re-gain sensation in your eye(s).
- Drive or use machines once 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**

**Usual dose:**

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

**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
- Scratch of the cornea with or without softening
- Clouding of the cornea
- Inflammation of the cornea, including the coloured part of the eye
- Shedding of dead eye surface cells
- Damage of the cornea
- Bloodshot eyes

Known side effects in the rest of the body include: drying or splitting of the skin on your fingertips 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**

ODAN-PROPARACAINE is stored refrigerated 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 [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- 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 0701D  
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 [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*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 prescribing information, prepared for health professionals can be obtained by contacting the sponsor, Odan Laboratories Ltd at:

1-800-387-9342

or

[www.odanlab.com](http://www.odanlab.com)

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