



# Optaloc™ 0.5%

Betaxolol 0.5%  
Sterile Eye Drops

## Description

Optaloc is a sterile ophthalmic solution containing Betaxolol Hydrochloride - a selective beta-adrenergic receptor blocking agent for topical administration into the eyes.

## Composition

Each ml Optaloc eye drops contains:

Active Substance: Betaxolol Hydrochloride BP equivalent to Betaxolol 5 mg.

Preservative: Benzalkonium Chloride 0.1 mg.

## Clinical Pharmacology

Betaxolol is a selective (beta-1-adrenergic) receptor blocking agent that does not have significant membrane stabilizing (local anaesthetic) activity and is free from intrinsic sympathomimetic action. When instilled into the eye, Betaxolol reduces elevated as well as normal intraocular pressure, whether or not accompanied by glaucoma. Optic nerve head damage and visual field loss are results of a sustained elevated intraocular pressure and poor ocular perfusion. The ocular hypotensive action of Betaxolol appears to be mediated by a reduction of aqueous production as demonstrated by tonography and aqueous fluorophotometry.

Betaxolol ophthalmic solution does not produce miosis or accommodative spasm which is frequently seen with miotic.

The onset of action with Betaxolol can generally be noted within 30 minutes and the maximal effect can usually be detected two hours after topical administration. A single dose provides a 12-hour reduction in intraocular pressure (IOP) and twice daily administration maintains the IOP below 22 mm Hg in most patients.

## Indications and Uses

Optaloc (Betaxolol) ophthalmic solution has been shown to be effective in lowering intraocular pressure and is indicated in the treatment of ocular hypertension and chronic open-angle glaucoma. May be used alone or in combination with other intraocular pressure lowering medication.

## Dosage and Administration

The usual dose is 1 drop of Optaloc eye drops in the affected eye(s) twice daily. In some patients, the intraocular pressure lowering response may require a few weeks to stabilize. Clinical follow-up should include a determination of the intraocular pressure during the first month of treatment. Thereafter, intraocular pressure should be determined on an individual basis at the judgment of the physician.

## Contraindications

Hypersensitivity to any component of this product. Betaxolol should not be used in patients with sinus bradycardia, atrioventricular block greater than first degree, cardiogenic shock, or patients with a history of overt cardiac failure.

## Precautions

In patients with angle-closure glaucoma, the immediate treatment objective is to re-open the angle by constriction of the pupil with miotic agent. Betaxolol has no effect on the pupil; therefore, Optaloc should be used with a miotic to reduce elevated intraocular pressure in angle-closure glaucoma. Beta-adrenergic blocking agents should be administered with caution in patients subjected to spontaneous hypoglycemia or to diabetic patients as these agents may mask the signs and symptoms of acute hypoglycemia.

## Side Effects

**Ocular:** Discomfort of short duration, occasional tearing has been reported. Rare instances of decreased corneal sensitivity, erythema, itching sensation, corneal punctate staining, keratitis, edema and photophobia have been reported.

**Systemic:** Systemic reactions following administration of Betaxolol hydrochloride ophthalmic solution 0.5% have been rarely reported. These include:

**Cardiovascular:** bradycardia, heart block, congestive heart failure.

**Respiratory:** bronchospasm, respiratory failure.

**Others:** Hives, toxic epidermal necrolysis, hair loss and glossitis.

## Use in Pregnancy & Lactation

**Pregnancy:** There are no adequate & well controlled studies in pregnant women. Betaxolol ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk.

**Lactation:** It is not known whether Betaxolol is excreted in human milk. The risk of hypoglycemia & bradycardia in nursing infant has not been evaluated. Breast feeding is not recommended during treatment.

## Drug Interactions

Betaxolol is an adrenergic blocking agent; therefore, caution should be exercised in patients using concomitant adrenergic psychotropic drug. In patients with angle-closure glaucoma, Betaxolol ophthalmic solution should be used with a miotic and not alone.

## Overdosage

No information is available on overdosage. A topical overdosage of Betaxolol ophthalmic solution may be flushed from the eye(s) with warm tap water.

## Pharmaceutical Precautions

Store at room temperature. It is desirable that the content should not be used more than one month after first opening of the bottle.

## Commercial Pack

Dropper bottle of 5 ml.

Manufactured by :



**POPULAR PHARMACEUTICALS LTD.**  
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