Each mL contains 10 mg carteolol HCl and the inactive ingredients: boric acid (0.005% as a preservative), sodium chloride, sodium phosphate, dibasic; sodium phosphate, monobasic; and water for injection. USP. The product has a pH range of 6.2 - 7.2.

**CLINICAL PHARMACOLOGY**

Carteolol Hydrochloride Ophthalmic Solution, USP 1% is a nonselective beta-adrenergic blocking agent with associated intrinsic sympathomimetic activity and without significant membrane-stabilizing activity.

Carteolol Hydrochloride Ophthalmic Solution, USP 1% reduces normal and elevated intraocular pressure (IOP) whether or not accompanied by glaucoma. The exact mechanism of the ocular hypotensive effect of beta-blockers has been defensibly demonstrated. In general, beta-adrenergic blockers reduce cardiac output in patients in good and poor cardiovascular health. In patients with severe impairment of myocardial function, beta-blockers may exhibit the sympathetic stimulation necessary to maintain adequate cardiac function. Beta-adrenergic blockers may also increase arm resistance in the brachial and tibial vessels due to decreased propyphosphorylase activity. Given topical twice daily in controlled clinical trials ranging from 1.5 to 3 months, Carteolol Hydrochloride Ophthalmic Solution, USP 1% produced a median percent reduction of IOP 22% to 25%. No significant effects were noted on corneal sensitivity, tear secretion, or patient use.

**INDICATIONS AND USAGE**

Carteolol Hydrochloride Ophthalmic Solution, USP 1%, has been shown to be effective in lowering intraocular pressure and may be used in patients with chronic open-angle glaucoma and intraocular hypertension. It may be used alone or in combination with other intraocular pressure lowering medications.

**CONTRAINDICATIONS**

Carteolol Hydrochloride Ophthalmic Solution, USP 1% is contraindicated in those individuals with bronchial asthma or with a history of bronchial asthma, or severe chronic obstructive pulmonary disease (see WARNINGS). Certain adrenergic, second- and third-degree atrioventricular block; overt cardiac failure (see WARNINGS); cardiogenic shock; or hypersensitivity to any component of this product.

**WARNINGS**

Carteolol Hydrochloride Ophthalmic Solution, USP 1% has not been detected in plasma following ocular instillation. However, as with other topically applied ophthalmic preparations, Carteolol Hydrochloride Ophthalmic Solution, USP 1% may be absorbed systemically. The same adverse reactions found with systemic administration of beta-adrenergic blocking agents may occur with topical administration. For example, topically applied ophthalmic preparations, Carteolol Hydrochloride Ophthalmic Solution, USP 1% may be absorbed systemically. The same adverse reactions found with systemic administration of beta-adrenergic blocking agents may occur with topical administration. For example, severe respiratory reactions and cardiac reactions, including death due to bronchospasm in patients with asthma and rarely death in association with cardiac failure, have been reported with systemic use of beta-adrenergic blocking agents (see CONTRAINDICATIONS). For topical use only. To prevent contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas of the eye.
Headache
Hypersensitivity, including localized and generalized rash
Administer a beta-stimulating agent such as isoproterenol and/or a theophylline derivative.

Signs and symptoms of keratitis, blepharoptosis, visual disturbances including refractive changes (due to corneal staining, and corneal sensitivity occurred occasionally).

Bronchospasm (predominantly in patients with pre-existing bronchospastic disease), respiratory failure (see WARNINGS).

Administer vasopressors such as intravenous dopamine, epinephrine or norepinephrine bitartrate.

Depression
Nausea


The following adverse reactions have been reported with ophthalmic use of beta-adrenergic blocking agents.

Cardiovascular:
Arrhythmia, syncope, heart block, congestive cardiac failure, cerebral ischemia, cerebral vascular accident, cerebral hemorrhage, congestive heart failure, peripheral circulatory collapse (see WARNINGS).

Skin:
Psychiatric:

Dosage and Administration
The usual dose is one drop of Carteolol Hydrochloride Ophthalmic Solution, USP 1%, in the affected eye(s) twice a day. If the patient's IOP is not at a satisfactory level on this regimen, concomitant therapy with pilocarpine and other miotics, and/or epinephrine or epinephrine, and/or systemically administered carbonic anhydrase inhibitors, such as acetazolamide, can be instituted.

The following additional adverse reactions have been reported with ophthalmic use of beta, and beta (nonselective) adrenergic receptor blocking agents.

Body As a Whole: Headache

Confusional: Ataxia, nystagmus

Digestive: Nausea

Endocrine: Masked symptoms of hypothyroidism in thyroid-dependent diabetics (see WARNINGS)

Respiratory:Bronchospasm (predominantly in patients with pre-existing bronchospastic disease), respiratory failure (see WARNINGS).

Other reactions associated with the oral use of nonselective adrenergic receptor blocking agents should be considered potential effects with ophthalmic use of these agents.

To report SUSPECTED ADVERSE REACTIONS, contact Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC, at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE
No specific information on emergency treatment of overdosage in humans is available. Should accidental ocular overdosage occur, flush eye(s) with water or normal saline. The most common effects expected with overdosage of a beta-adrenergic blocking agent and beta-blockers, bronchospasm, congestive heart failure and hypotension.

In cases of ingestion, treatment with Carteolol Hydrochloride Ophthalmic Solution, USP 1% should be discontinued and gastric lavage considered. The patient should be closely observed and vital signs carefully monitored. The prolonged effects of carteolol must be considered when determining the duration of corrective therapy. On the basis of the pharmacology profile, the following additional measures should be considered as appropriate:

Symptomatic: Sinus Bradycardia or Heart Block: Administer atropine. If there is no response to vagal block, administer isoproterenol cautiously.

Dosage and Administration
The usual dose is one drop of Carteolol Hydrochloride Ophthalmic Solution, USP 1%, in the affected eye(s) twice a day.

If the patient's IOP is not at a satisfactory level on this regimen, concomitant therapy with pilocarpine and other miotics, and/or epinephrine or epinephrine, and/or systemically administered carbonic anhydrase inhibitors, such as acetazolamide, can be instituted.

DOSAGE AND ADMINISTRATION
The usual dose is one drop of Carteolol Hydrochloride Ophthalmic Solution, USP 1%, in the affected eye(s) twice a day.

If the patient's IOP is not at a satisfactory level on this regimen, concomitant therapy with pilocarpine and other miotics, and/or epinephrine or epinephrine, and/or systemically administered carbonic anhydrase inhibitors, such as acetazolamide, can be instituted.

HOW SUPPLIED
Carteolol Hydrochloride Ophthalmic Solution, USP 1%, is supplied as a sterile ophthalmic solution in a plastic bottle with a yellow cap and controlled dropper tip in the following sizes:

- 5 mL bottles - NDC 24208-367-05
- 10 mL bottles - NDC 24208-367-10
- 15 mL bottles - NDC 24208-367-15


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Approved

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