

HOMATROPINE HYDROBROMIDE OPHTHALMIC- homatropine hydrobromide solution
Altaire Pharmaceuticals Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Homatropine Hydrobromide Ophthalmic Solution, USP

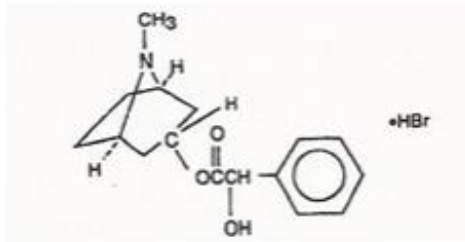
**HOMATROPINE HYDROBROMIDE
OPHTHALMIC SOLUTION, USP**
Rx only

Established name:

Homatropine Hydrobromide

Chemical Name:

Benzeneacetic acid, α -hydroxy-, 8-methyl-8-azabicyclo [3.2.1]-oct-3-yl ester, hydrobromide, *endo*-(\pm)-. The active ingredient is represented by the chemical structure:



Each mL contains: Active: Homatropine Hydrobromide 5.0%. Preservative: Benzalkonium Chloride 0.005%. Inactive: Boric Acid, Edetate Disodium, Potassium Chloride, Water for Injection. Boric Acid or Sodium Carbonate may be added to adjust the pH.

INDICATIONS AND USAGE:

A moderately long-acting mydriatic and cycloplegic for cycloplegic refraction and in the treatment of inflammatory conditions of the uveal tract. For pre and postoperative states when mydriasis is required. Use as an optical aid in some cases of axial lens opacities.

DOSAGE AND ADMINISTRATION:

For refraction, instill one or two drops topically in the eye(s). May be repeated in five or ten minutes if necessary. For uveitis, instill one or two drops topically up to every three to four hours. Individuals with heavily pigmented irides may require larger doses.

CONTRAINDICATIONS:

Contraindicated in persons with primary glaucoma or a tendency toward glaucoma, e.g. narrow anterior chamber angle, and in those persons showing hypersensitivity to any component of this preparation.

WARNING:

For topical use only – not for injection. Risk-benefit should be considered when the following medical problems exist: keratoconus (Homatropine may produce fixed dilated pupil); Down's syndrome, children with brain damage and the elderly (increased susceptibility). In infants and small children, use with extreme caution. Excessive use in pediatric patients or certain individuals with a history of susceptibility to belladonna alkaloids may produce systemic symptoms of homatropine poisoning (see overdose section).

PRECAUTIONS:

General.

To avoid excessive systemic absorption, the lacrimal sac should be compressed by digital pressure for two to three minutes after installation. To avoid inducing angle closure glaucoma, an estimation of the depth of the angle of the anterior chamber should be made. Excessive topical use of this drug can potentially lead to a confusional state characterized by delirium, agitation, and rarely coma. This state is more apt to occur in the pediatric and geriatric age groups. The specific anti-dote for this systemic anticholinergic syndrome is injectable physostigmine salicylate.

Information to Patients.

Patient should be advised not to drive or engage in other hazardous activities while pupils are dilated. Patient may experience sensitivity to light and should protect eyes in bright illumination during dilation. Parents should be warned not to get this preparation in their child's mouth and to wash their own hands and the child's hands following administration. Do not touch dropper tip to any surface, as this may contaminate the solution.

ADVERSE REACTIONS:

Transient symptoms of stinging and burning may occur. Prolonged use may produce local irritation characterized by follicular conjunctivitis, vascular congestion, edema, exudates, and an eczematoid dermatitis. Thirst or dryness of mouth, eye irritation not present before therapy, or increased sensitivity of eyes to light may occur.

To report SUSPECTED ADVERSE REACTIONS, contact Altaire Pharmaceuticals, Inc. at (800)-258-2471.

Pregnancy.

Pregnancy Category C. Animal reproduction studies have not been conducted with homatropine hydrobromide. It is also not known whether homatropine hydrobromide

can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Homatropine Hydrobromide should be given 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 homatropine hydrobromide is administered to a nursing woman

Pediatric Use:

Homatropine should not be used during the first three months of life due to a possible association between the cycloplegia produced and the development of amblyopia.

Safety and effectiveness in pediatric patients have not been established.

OVERDOSAGE:

When signs and symptoms of homatropine toxicity develop (see adverse reaction section), physostigmine should be administered parenterally (for dosage refer to Goodman & Gilman or other pharmacology reference). In infants and pediatric patients, the body surface must be kept moist.

DESCRIPTION:

Homatropine hydrobromide is an anticholinergic prepared as a sterile topical ophthalmic solution.

CLINICAL PHARMACOLOGY:

This anticholinergic preparation blocks the responses of the sphincter muscle of the iris and the accommodative muscle of the ciliary body to cholinergic stimulation, producing pupillary dilation (mydriasis) and paralysis of accommodation (cycloplegia).

Carcinogenesis, Mutagenesis, Impairment of Fertility:

There have been no long-term studies done using homatropine hydrobromide in animals to evaluate carcinogenic potential.

HOW SUPPLIED:

5mL size in a white plastic bottle
5mL - NDC 59390-192-05

Storage:

Store at 15° - 30°C (59°- 86°F).

Caution: Federal (USA) law prohibits dispensing without prescription.

Mfd. by: Altaire Pharmaceuticals, Inc

Aquebogue, NY 11931

R05/13

F# 16545

PRINCIPAL DISPLAY PANEL

NDC 59390-192-05

Homatropaire

Homatropine Hydrobromide

Ophthalmic Solution, USP 5%

5 mL- Sterile

Rx Only

59390-192-05
A STERILE OPHTHALMIC SOLUTION
EACH ML CONTAINS: Homatropine Hydrobromide 50 mg in buffered aqueous solution containing boric acid, potassium chloride, edetate disodium and water for injection, preserved with benzalkonium chloride.
Mfd. by:
ALTAIRE Pharmaceuticals, Inc.
Aquebogue, NY 11931

NDC 59390-192-05
HOMATROPAIRE
HOMATROPINE
HYDROBROMIDE
OPHTHALMIC
SOLUTION, USP 5%
5 mL-Sterile
Rx only

USUAL DOSE: See package insert for full prescribing information. Protect from light, store at room temperature 15°-30°C (59°-86°F). Keep tightly closed. Keep this and all drugs out of the reach of children.

DO NOT USE IF IMPRINTED SEAL ON CAP IS TORN, BROKEN OR MISSING.

R0711

HOMATROPINE HYDROBROMIDE OPHTHALMIC

homatropine hydrobromide solution

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:59390-192 |
| Route of Administration | OPHTHALMIC | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|------------------|
| HOMATROPINE HYDROBROMIDE (UNII: BEW7469QZ0) (HOMATROPINE - UNII:8QS6WCL55Z) | HOMATROPINE HYDROBROMIDE | 50 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |
| BORIC ACID (UNII: R57ZHV85D4) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) | |
| WATER (UNII: 059QF0KOOR) | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59390-192-05 | 5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/01/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug other | | 06/01/2018 | |

Labeler - Altaire Pharmaceuticals Inc. (786790378)

Revised: 10/2022

Altaire Pharmaceuticals Inc.