For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

Homisenz®

Eye Drops

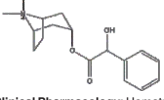
(Homatropine Eye Drops IP)

COMPOSITION:

Homatropine Hydrobromide IP..... 2.0%w/v
Benzalkonium Chloride Solution IP 0.02%v/v
(As preservative)
Water for Injections IP ..... q.s.

Inactive Ingredients: Boric Acid, Disodium Edetate, Potassium Chloride in Water for Injection.

Description : Homatropine hydrobromide belongs to a class of drugs known as anticholinergics. It works by widening (dilating) the pupil of the eye.
Chemical Name: Benzeneacetic acid, α -hydroxy-, 8-methyl-8-azabicyclo [3.2.1]-oct-3-yl ester, hydrobromide, endo-(±)-.
The active ingredient is represented by the chemical structure:



Clinical Pharmacology: Homatropine Eye Drop 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).
Indications And Usage: Homatropine Eye Drop is used before eye examinations and to treat an eye condition called uveitis. It acts by enlarging the pupil of the eyes and helps the doctor visualize the eye more closely. It reduces redness and swelling in the eyes after cataract surgery
In Eye examination: Homatropine Eye Drop helps to increase the size of the pupil which helps in thorough examination of the eyes and its associated structures. It is used by an eye specialist and should not be self-administered.
In Uveitis: The middle layer in the inner wall of the eye is called uvea and any inflammation in this layer is called uveitis. This may cause sudden noticeable symptoms such as pain, redness, blurred vision, swelling etc. It may even occur after an eye procedure of surgery such as cataract surgery. Homatropine Eye Drop helps relieve these symptoms and improves the eye health. It should be used as advised by the doctor to get the most benefit.
Dosage and Administration: Shake well before use.
For refraction, instil one or two drops topically in the eye(s). May be repeated in five or ten minutes if necessary or as directed by Physician.
For uveitis, instil one or two drops topically up to every three to four hours. Individuals with heavily pigmented iris may require larger doses.
Side Effects: Most side effects do not require any medical attention and disappear as your body adjusts to the medicine. Consult your doctor if they persist or if you are worried about them.
Severe side effects of Homatropine

- Eye irritation
- Follicular conjunctivitis
- Stinging in the eyes
- Dryness in mouth
- Eczematoid dermatitis
- Feeling thirsty
- Increased sensitivity to light
- Burning eyes
- Edema (swelling)
- Vascular engorgement
- Exudate

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 confusion state characterized by delirium, agitation, and rarely coma. This state is more apt to occur in the paediatric and geriatric age groups. The specific anti-dote for this systemic anticholinergic syndrome is injectable physostigmine salicylate.

Pregnancy Category C: Animal reproduction studies have not been conducted with homatropine hydrobromine. It is also not known whether Homatropine hydrobromide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Homamtropine hydrobromide should be given to a pregnant woman ony 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.

Carcinogenesis, Mutagenesis, Impairment of Fertility: There have been no long-term studies done using homatropine hydrobromide in animals to evaluate carcinogenic potential.

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.

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.

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 paediatric patients, the body surface must be kept moist.

Storage: Store below 30°C, Do not freeze, Protect from light Use the solution within one month after opening the container.

Do not touch the tip of the container to any surface.

KEEP OUT OF REACH OF CHILDREN

NOT FOR INJECTION

FOR EXTERNAL USE ONLY

Presentation:

Homisenz is a sterile solution supplied in plastic opaque dropper bottle with a cap, containing 5 mL of the solution.

Directions for use:

Turn the tamper proof cap anti clockwise to break the seal and remove the cap.

Remove and discard the tamper proof ring from the container.

Tilt your head back. Gently pull your lower eyelid downwards to form a pocket between your eyelid and your eye, look up.

Turn the container upside down, place the dropper tip close to your eye but be careful not to touch your eye with it and gently press the container with thumb and index finger to dispense the drop.

Replace the cap by turning clockwise direction until it is firmly touching the bottle. Do not overtighten the cap.

Manufactured in INDIA by :

Senses Pharmaceuticals Pvt. Ltd.,

No.77, 3rd Road, Bommasandra Industrial Area,
Bommasandra 4th Phase, Bengaluru - 560 099.

® Registered Trademark

HMZPI - 02

Month of publication of pack insert: October 2026