Atrokid ™

Eye drops

1. Atropine Sulphate 0.01% w/v eye drops

2. Qualitative and Quantitative composition

Atropine Sulphate IP..... 0.01% w/v

Stabilized Oxychloro Complex ..... 0.005% w/v

(As preservative)

Sterile Aqueous Buffered Base..... q.s.

3. Dosage form and strength

Each 5 ml contains Atropine Sulphate IP ..... 0.01% w/v

4. Clinical particulars

4.1 Therapeutic indication

In Treatment of Myopia

Myopia or near-sightedness is an eye disorder in which your child may have difficulty seeing distant objects but can see objects that are near clearly. Childhood myopia can be diagnosed at a very early age and can increase gradually from adolescence to adulthood. A low dose of Atropine 0.01% Eye Drop, if started at an early age, can significantly slow down the progression of myopia, preventing the progression of near-sightedness in the future.

4.2 Posology and method of administration

One drop in each eye every day.

4.3 Contraindication

Atropine generally is contraindicated in patients with glaucoma, pyloric stenosis, thyrotoxicosis, urinary tract obstruction, ileus, and hypermetropia.

4.4 Special warnings and precautions for use

Always wash the hands thoroughly with soap and hot water before and after using atropine 0.01% Eye Drop. Doing so will help avoid the risk of any infection. For instilling the medicine, ask your child to lie down and look up and to the other side. Make sure your child remains still and calm while you are putting the medicine. Put the medicine drops in the lower eyelid, directed away from the nose. After this, ask your child to keep their eyes closed for some time so that the medicine doesn't spill out and gets absorbed properly. Abstain your child from rubbing their eyes soon after putting the medicine as it can lead to redness or irritation. Your child should not wear any sort of

contact lenses while on treatment with Atropine 0.01% Eye Drop as this medicine can damage the lenses. Do not abruptly stop the medicine by yourself, even if your child starts to feel better. Continue the medicine until the prescribed course is complete. Consult your child's doctor in case of any confusion.

4.5 Drug interactions

No interaction found/established

4.6 Use in special population

Caution is necessary for use with elderly patients, chronic lung disease patients, acute angle glaucoma, obstructive diseases (uropathy, toxic megacolon, paralytic ileus, pyloric stenosis, prostatic hypertrophy), myasthenia gravis, or in situations with environmental heat exposure.

4.7 Effects on ability to drive and use machine

Not applicable

4.8 Undesirable effects

This medicine may have some minor and temporary side effects such as blurry vision, photophobia, eye irritation, and stinging in the eyes. These episodes should start receding after a few doses. However, if these side effects persist or become bothersome for your child, report to the doctor without any delay.

4.9 Overdose

In case of overdose excessive dilation may appear. If overdose occurs, treatment should be symptomatic and supportive.

5 Pharmacological properties

Mechanism of action

Atropine is most effective therapy to control myopic condition. Recent clinical trials demonstrated low-dose atropine eye drops such as 0.01% resulted in retardation of myopia progression.

Two primary mechanisms of atropine

1) Relaxation of Suspensory ligaments

Atropine relaxes some of the tension on the suspensory ligament (causing relaxation), modifying the shape of the lens.

2) Blocking action of acetylcholine (pupil dilation)

Atropine is a nonselective muscarinic antagonist, i.e., it competes for binding sites on all muscarinic receptors, thus blocking the action of acetylcholine and causes mydriasis.

5.2 Pharmacodynamic properties

Atropine is an antimuscarinic agent that antagonizes the effects of acetylcholine. In small doses, atropine slows heart rate, and tachycardia develops due to paralysis of vagal control. Compared to scopolamine, atropine has a more potent and prolonged effect on the heart, intestine and bronchial muscle, but a weaker effect on the iris, ciliary body and certain secretory glands.

Atropine leads to increased respiratory rate and depth of respiration, possibly due to the drug-induced bronchiolar dilatation rather than its mild effect on vagal excitation.

At an adequate dose, atropine abolishes different types of reflex vagal cardiac slowing or asystole. Atropine can be used to prevent or abolish bradycardia or asystole induced by the injection of choline esters, anticholinesterase agents or other parasympathomimetic drugs, and cardiac arrest produced by stimulation of the vagus. When vagal activity is an etiologic factor, atropine may also lessen the degree of partial heart block. In clinical doses, atropine counteracts the peripheral dilatation and abrupt decrease in blood pressure produced by choline esters. However, when given by itself, atropine does not exert a striking or uniform effect on blood vessels or blood pressure. The use of topical atropine in the eye induces mydriasis by inhibiting the contraction of the circular pupillary sphincter muscle normally stimulated by acetylcholine. This results in the contraction of the countering radial pupillary dilator muscle and pupil dilation.

5.3 Pharmacokinetic properties

The protein binding of atropine ranges from 14% to 44% and is saturable between 2 and 20 µg/mL.

Approximately 13 to 50% of atropine is excreted unchanged in the urine.

Atropine is mainly metabolized by enzymatic hydrolysis in the liver. The major metabolites of atropine are noratropine, atropin-n-oxide, tropine, and tropic acid. The metabolism of atropine is inhibited by organophosphate pesticides.

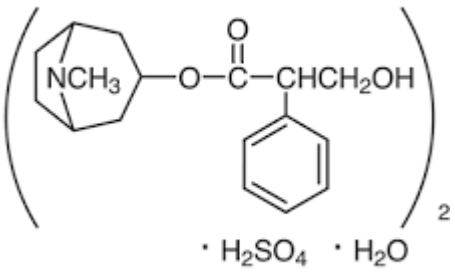
6 Nonclinical properties

6.2 Animal Toxicology or Pharmacology

Not required.

7. Description

3-hydroxy-2-phenylpropanoic acid (8-methyl-8-azabicyclo[3.2.1]octan-3-yl) ester is a tropane alkaloid.



8. Pharmaceutical particulars

8.1 Incompatibilities: There are no known incompatibilities.

8.2 Shelf-life: 18 months.

8.3 Packaging Information: Ophthalmic solution 5 ml.

8.4 Storage and handling instructions: Store in a dry, well ventilated place at a temperature not exceeding 25^{0}C. Do not freeze.

Keep medicines out of reach of children.

9. Patient Counselling Information

9.1 Adverse reactions: Refer part 4.8

9.2 Drug Interactions: Refer part 4.5

9.3 Dosage: Refer part 3

9.4 Storage: Refer part 8.4

9.5 Risk factors: Refer part 4.4

9.6 Self-monitoring information: NA

9.7 Information on when to contact a health care provider or seek emergency help: Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing Physician.

9.8 Contraindications: Refer part 4.3

10. Details of manufacturer: Sayora Pharma Pvt Ltd.

11. License number date: 599 B(H)

12. Date of revision: September 2023