Atropine Sulfate Ophthalmic Ointment, 1% (Sterile)

Rx only

DESCRIPTION: Atropine Sulfate Ophthalmic Ointment, 1% is a sterile topical anticholinergic for ophthalmic use. The active ingredient is represented by the chemical structural formula:

\[
\text{Atropine Sulfate, 1% (10 mg)}; \quad \text{INACTIVES:} \quad \text{Lanolin oil, mineral oil, purified water, and white petrolatum.}
\]

Chemical Name: Benzenecarboxylic acid, α-(hydroxymethyl)-, 8-methyl-8-azabicyclo-[3.2.1]oct-3-yl ester, endo-1-, sulfate (2:1) (salt), monohydrate.

Each gram contains:

ACTIVE: Atropine Sulfate, 1% (10 mg); INACTIVES: Lanolin oil, mineral oil, purified water, and white petrolatum.

INDICATIONS AND USAGE

For mydriasis and/or cycloplegia. For cycloplegic refraction, for pupillary dilation desired in inflammatory conditions of the eye and uveal tract.

PRECAUTIONS

To avoid excessive systemic absorption, the lacrimal sac should be compressed by digital pressure for two to three minutes after instillation. To avoid inducing angle closure glaucoma, an estimation of the depth of the angle of the anterior chamber should be made. Administration of atropine in infants requires great caution.

Patient Warning: Patients should be advised not to drive or engage in other hazardous activities while pupils are dilated. Patients may experience sensitivity to light and should protect eyes in bright illumination during dilation.

OVERDOSAGE

Systemic atropine toxicity is manifested by flushing and dryness of the skin (a rash may be present in pediatric patients), blurred vision, a rapid and irregular pulse, fever, abdominal distention in infants, mental alteration (hallucinosis) and loss of neuromuscular coordination.

Adverse reactions may produce local irritation characterized by follicular conjunctivitis, vascular congestion, edema, exudate, and an eczematoid dermatitis. Severe reactions are manifested by hypotension with progressive respiratory depression. coma and death have been reported in the very young.

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.

DOSEAGE AND ADMINISTRATION

Apply a small amount of ointment to the conjunctival sac once or twice a day, as directed by a physician.

FOR OPHTHALMIC USE ONLY

How supplied

Atropine Sulfate Ophthalmic Ointment, 1% is supplied in an ophthalmic tip applicator tube in the following size:

3.5 g tubes - NDC 24208-825-55


KEEP OUT OF REACH OF CHILDREN

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