

1.6.3 Patient Information leaflet (PIL)

Interactions with other medications

Peripheral and central anticholinergics effects may be additive to those of other drugs with anticholinergics side effects, like tricyclic antidepressants, antiparkinsonism drugs, antispasmodic agents, antihistamines, phenothiazines, quinidine, and disopyramide.

Pregnancy & Lactation use

Precautions

Give to a pregnant woman only if clearly needed. These agents are compatible with breastfeeding. Excessive use in children and in certain susceptible individuals may produce systemic toxic symptoms. Use with extreme caution in infants.

Adverse reactions

Increased intraocular pressure; transient stinging / burning; irritation with prolonged use. Dryness of the mouth and skin; blurred vision; photophobia with or without corneal staining; tachycardia; headache; parasympathetic stimulation; somnolence; visual hallucinations.

Dosage and Administration

Apply topically to the eye as directed by the physician.

Overdosage

Flush eye with water or normal saline. Use of a topical miotic may be required. If accidentally ingested, induce emesis or gastric lavage.

Supply

Atrop eye drops is supplied in sterile white opaque plastic container.

Storage

Store below 30° C

Manufacturer:

 **Aurolab**
No.1, Sivagangai Main Road,
Veerapanjan, Madurai - 625 020. (INDIA)
Tel : 91-452-3096100
Fax : 91-452-2446200
Email : info@aurolab.com
Web : www.aurolab.com

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Instructions for use leaflet

ATROP

(Atropine sulfate Ophthalmic Solution 1% w/v)

Description

Atrop 1% w/v solution is a sterile, clear, colorless and contains 10 mg of Atropine Sulphate and 0.1 mg of Benzalkonium chloride as preservative in 1 ml.

Clinical Pharmacology

The anticholinergic effect 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

Atrop 1% w/v used in Cycloplegic refraction or pupil dilation in acute inflammatory conditions of iris and uveal tract.

Contraindications

Primary glaucoma or a tendency toward glaucoma (eg. narrow anterior chamber angle); hypersensitivity to belladonna alkaloids or any component of the products; adhesions (synechiae) between the iris and the lens; children who have previously had a severe systemic reaction to atropine.

Warnings

Not for injection. For topical ophthalmic use only. Do not touch the nozzle tip to any surface, since this may contaminate the solution. Determine the intraocular tension and the depth of the angle of the anterior chamber before and during use to avoid glaucoma attacks. Use these products with caution in the elderly and others where increased IOP may be encountered.

Precautions

Avoid excessive systemic absorption by compressing the lacrimal sac by digital pressure during and for 2 to 3 minutes after instillation. Down's syndrome / children with brain damage patients may demonstrate a hyper reactive response to topical atropine. May produce drowsiness, blurred vision or sensitivity to light (due to dilated pupils); observe caution while driving or performing other tasks requiring alertness, coordination or physical dexterity.