1.6 Product Information

1.6.1 Summary of Product characteristics.

ATROP (Atropine Sulfate Ophthalmic solution USP 1.0 % w/v)

1. Name of the medicinal product
ATROP

2. Qualitative and quantitative composition
Each ml contains,

Atropine Sulfate	USP	1 %w/v
Benzalkonium chloride	BP	0.01%w/v
Excipients	q.s	

3. Pharmaceutical form
Ophthalmic Solution.
Clear, colorless aqueous sterile solution, practically free from visible particles.

4. Clinical particulars
4.1 Therapeutic indications

1. Atropine Sulfate is used as a mydriatic and cycloplegic agent.
2. For pre-operative use in ophthalmic surgery.
3. For treatment of uveitis and refraction.

4.2 Posology and method of administration

Adults (including the elderly):

Uveitis: 1 drop 2-3 times a day.

Refraction: 1 drop twice a day prior to examination.

4.3 Contraindications

Use in patients with a known hypersensitivity to atropine.

Due to the risk of precipitating acute attack, do not use in cases of confirmed narrow-angle glaucoma or where latent narrow angle glaucoma is suspected. If in doubt it is recommended that an alternative preparation is used.

4.4 Special warnings and precautions for use

This Product should be used with caution in an inflamed eye, as hyperaemia greatly increases the rate of systemic absorption through the conjunctiva.
Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (this blocks the passage of the drops via

the nasolacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisible in children.)

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

The safety for use in pregnancy and lactation has not been established, therefore, use only when directed by a physician.

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision on instillation.Warn patients not to drive or operate hazardous machinery until vision is clear.

4.8 Undesirable effects

Transient stinging may occur on instillation.

Side effects include local irritation, hyperaemia, oedema and conjunctivitis, especially with repeated administration.
Side effects rarely occur but include anticholinergic effects such as dry mouth and skin, flushing increased body temperature, urinary symptoms, gastrointestinal symptoms and tachycardia .These effects are more likely to occur in infacts and children.

4.9 Overdose

Systemic reaction to topical atropine are unlikely at normal doses. Symptoms which can occur following an overdose, however, include anticholinegic effects. Cardiovascular changes (tachycardia, atrial arrhythmias, atrio-ventricular dissociation) and central nervous system effects (confusion, ataxia, restlessness, hallucination , convulsions).Treatment is supportive.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Atropine Sulfate is a competitive antagonist of acetylcholine at postganglionic cholinergic (parasympathetic) nerve endings.
Atropine does not discriminate between the recently discovered muscarinic receptor sub types M1 (in parasympathetic ganglia of the submucous plexus, with high affinity for selecting antimuscarinic pirenzapine) and M2 (low affinity for pirenzepine and occurring predominantly in heart and smooth muscle.)

5.2 Pharmacokinetic Properties

Atropine is well absorbed from the small bowel and not at all from the stomach .thus are the effects of oral dosing much slower in onset than after parentral dosing. Atropine is also absorbed by mucous

membrane but less readily from the eye and skin, although significant toxicity can sometimes occur through absorption of excessive eye drops.

Atropine has a volume of distribution of 1 - 61/kg .Protein binding is moderate, with approximately 50% of the drug bound in plasma .Its plasma clearance are 8ml/min/kg.

Only traces of atropine are found in breast milk. The Drug readily crosses the blood –brain barrier and may cause confusion and delirium post-operatively.It crosses the placenta readily.

Atropine is metabolised by hepatic oxidation and conjugation to inactive metabolites, with about 2% undergoing hydrolysis to tropine and tropic acid. About 30% of the dose is excreted unchanged in the urine. Only trace amounts of the dose are eliminated in the faeces.

There is some evidence of prolonged elimination in elderly subjects.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. Pharmaceutical particulars

6.1 List of excipients

Boric acid BP
Benzalkonium chloride BP
Purified water BP

6.2 Incompatibilities

None known.

6.3 Shelf life

24months unopened.
Discard 30 days after first opening.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

5 ml filled in 10ml Low density polyethylene container with HDPE cap and Nozzle. Such 10ml is packed in a monocarton with package insert.

6.6 Special precautions for disposal and other handling

There is no special requirement for disposal.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

Aurolab, No.1,
Sivagangai Main road,
Veerapanjan,
Madurai - 625020, India.

No.1 Sivagangai Main Road, Veerapanjan, Madurai- 625 020, India,Tel: 91 452 309 6100
Fax: 91 452 244 6200, E.mail: info@aurolab.com Web: www.aurolab.com

8. Marketing authorisation number(s)
TN00002387

9. Date of renewal of the authorisation
11.07.2022

10. Date of revision of the text
Not Applicable