

New Zealand Data Sheet

1. ATROPT EYE DROPS (Atropine sulfate 1%)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 mL contains 10 mg atropine Sulfate (1 %).

Atropine Sulfate exists as odourless, colourless crystals or white crystalline powder. It effloresces in dry air.

Atropine Sulfate is soluble in water (1 in 0.5), in boiling water (1 in 2.5), in alcohol (1 in 5), in glycerol (1 in 2.5), practically insoluble in chloroform and ether. A 2% solution in water has a pH of 4.5 to 6.2. Solutions may be sterilised by autoclave.

Atropine Sulfate is both a mydriatic and cycloplegic and has the following molecular formula: $(C_{17}H_{23}NO_3)_2, H_2SO_4, H_2O$. Relative molecular mass is 694.8.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

ATROPT EYE DROPS contains atropine Sulfate (1%) in a sterile aqueous base. A clear, or almost clear, slightly viscous, colourless liquid which foams on shaking. Odourless.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ATROPT EYE DROPS are indicated where it is necessary to dilate the pupil and paralyse accommodation.

4.2 Dose and method of administration

Instil one drop into the eye as required for treatment. To minimise the risk of systemic absorption, gentle pressure should be applied to the tear duct for one minute after application.

4.3 Contraindications

ATROPT EYE DROPS are contraindicated in the presence of angle closure glaucoma or where angle closure glaucoma is suspected. If used in glaucoma susceptible patients, an estimation of the depth of the angle of the anterior chamber should be performed prior to the initiation of therapy.

Hypersensitivity to any ingredient in ATROPT EYE DROPS.

4.4 Special warnings and precautions for use

Patients treated prior to ophthalmic examination should be escorted to and from the surgery.

Use in Children

ATROPT EYE DROPS should be used with extreme caution, if at all, in infants and small children and in children with spastic paralysis or brain damage, due to their increased susceptibility to the systemic effects of the medicine.

Atropine Sulfate should not be used in children who have previously had severe systemic reaction to atropine. An increased susceptibility to atropine has been reported in infants and young children and in children with blonde hair, blue eyes, Down's Syndrome, spastic paralysis, or brain damage; therefore, atropine should be used with great caution in these patients.

Use in the Elderly

Geriatric patients are more susceptible to the effects of atropine, thus increasing the potential for systemic side effects.

Carcinogenicity, Mutagenicity, Impairment of Fertility

Studies have not been performed in either animals or humans to evaluate the potential carcinogenic, mutagenic or fertility impairing effects of atropine. No significant effects have been reported.

4.5 Interaction with other medicines and other forms of interaction**Anticholinergics**

If significant systemic absorption of ophthalmic atropine occurs, concurrent use of other anticholinergics or medications with anticholinergic activity may result in potentiated anticholinergic effects.

Antiglaucoma agents (cholinergic, long-acting, ophthalmic)

Concurrent use with atropine may antagonize the antiglaucoma and miotic actions of ophthalmic long-acting cholinergic anti-glaucoma agents, such as demecarium, ecothiophate, and isofluorophate; concurrent use with atropine may also antagonize the antiaccommodative convergence effects of these medications when they are used for the treatment of strabismus.

Antimyasthenics, potassium citrate, potassium supplements

If significant systemic absorption of ophthalmic atropine occurs, concurrent use may increase the chance of toxicity and/or side effects of these systemic medications because of the anti-cholinergic-induced slowing of gastrointestinal motility.

Carbachol, physostigmine or pilocarpine

Concurrent use with atropine may interfere with the antiglaucoma action of carbachol, physostigmine or pilocarpine. Also, concurrent use may counteract the mydriatic effect of atropine; this counteraction may be used to therapeutic advantage.

CNS depression-producing medications

If significant absorption of systemic atropine occurs, concurrent use of medications having CNS effects, such as antiemetic agents, phenothiazines, or barbiturates, may result in opisthotonos, convulsions, coma, and extrapyramidal symptoms.

4.6 Fertility, pregnancy and lactation

Fertility

No data available.

Pregnancy

Atropine Sulfate may be systemically absorbed after ocular administration; however, significant effects on the foetus have not been reported.

Lactation

Systemically absorbed atropine Sulfate is distributed into breast milk in very small amounts. It may cause adverse effects, such as rapid pulse, fever, or dry skin, in nursing infants of mothers using ophthalmic atropine.

4.7 Effects on ability to drive and use machines

No data available.

4.8 Undesirable effects

The following adverse reactions have been reported:

Ophthalmic

- Incidence common: Blurred vision.
- Incidence less frequent to rare: Conjunctival irritation, follicular conjunctivitis, increased intraocular pressure (especially in patients with closed-angle glaucoma), increased sensitivity to light, swelling of eyelids.

Systemic toxicity may occur in susceptible patients, particularly children. Such effects include:

Gastrointestinal

- Incidence less frequent to rare: Dryness of the mouth with difficulty in swallowing or talking, thirst, abdominal distention in infants.

Respiratory

- Incidence less frequent to rare: Reduced bronchial secretions, respiratory depression.

Dermatological

- Incidence less frequent to rare: Flushing and dryness of the skin, rash, dermatitis.

Cardiovascular

- Incidence less frequent to rare: Rapid and irregular pulse, hyperaemia, cardiac arrhythmias, hypotension.

Neurological

- Incidence less frequent to rare: Fever, clumsiness or unsteadiness, confusion or unusual behaviour, dizziness, hallucinations, slurred speech, unusual drowsiness, tiredness or weakness.

Musculoskeletal

- Incidence less frequent to rare: Loss of neuromuscular co-ordination, oedema.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>

4.9 Overdose

Signs of overdosage are similar to those described as systemic effects (see section 4.8, Undesirable effects). Treatment is symptomatic and supportive.

For accidental ingestion, emesis or gastric lavage with 4% tannic acid solution is recommended.

For systemic effects, 0.2 to 1mg (0.2mg in children) physostigmine should be administered intravenously, as a dilution containing 1mg in 5ml of normal saline. The solution should be injected over a period of not less than 2 minutes. Dosage may be repeated every 5 minutes up to a total dose of 2mg in children and 6mg in adults in each 30 minute period. Physostigmine is contraindicated in hypertensive reactions. ECG monitoring is recommended during physostigmine administration.

Excitement may be controlled by diazepam or a short acting barbiturate.

It is recommended that 1mg of atropine be available for immediate injection if the physostigmine causes bradycardia, convulsion, or bronchoconstriction.

Supportive therapy may require oxygen and assisted respiration; cool water baths for fever, especially in children; and catheterization for urinary retention. In infants and small children, the body surface should be kept moist.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).}

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Atropine is a belladonna alkaloid. Atropine Sulfate acts in the eye to block the action of acetylcholine, relaxing the cholinergically innervated sphincter muscle of the iris. This results in dilation of the pupil (mydriasis). The cholinergic stimulation of the accommodative ciliary muscle of the lens is also blocked. This results in paralysis of accommodation (cycloplegia). Effects on accommodation may last 6 days; mydriasis may persist for 12 days.

5.2 Pharmacokinetic properties

Atropine is readily absorbed from the gastrointestinal tract; it is also readily absorbed from mucous membranes, the eye, and to some extent through intact skin. It is rapidly cleared from the blood and is distributed throughout the body. It crosses the blood-brain barrier. It is incompletely metabolised in the liver and is excreted in the urine as unchanged medicine and metabolites. A half-life of 4 hours has been reported.

Atropine Sulfate has a slower onset and more prolonged effects than most other anticholinergics. Maximum mydriatic effect occurs in around 30-40 minutes. Maximum cycloplegia takes several hours. Mydriasis usually lasts 7 to 12 days and cycloplegia persists for 14 days or longer. Onset of effects and duration may be prolonged in heavily pigmented eyes.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate dihydrate, benzalkonium chloride, hypromellose, boric acid, water.

6.2 Incompatibilities

No data available.

6.3 Shelf-life

24 months from the date of manufacture.

6.4 Special precautions for storage

Store below 25°C. Protect from light.

6.5 Nature and contents of container

ATROPT EYE DROPS 1%: 15ml plastic dropper bottles with tamper seals.

6.6 Special precautions for disposal (and other handling)

No data available.

7. MEDICINE SCHEDULE

Prescription Medicine

8. SPONSOR

Pharmacy Retailing (NZ) Limited Trading as Healthcare Logistics
58 Richard Pearce Drive
Airport Oaks
Auckland

9. DATE OF FIRST APPROVAL

13th July 2010

10. DATE OF REVISION OF THE TEXT

May 2019

SUMMARY TABLE OF CHANGES

Section Changed	Summary of New Information
Format of Data Sheet	As per new European SmPC style format