AUSTRALIAN PRODUCT INFORMATION – MINIMS ATROPINE SULPHATE (ATROPINE SULFATE MONOHYDRATE) EYE DROPS

1 NAME OF THE MEDICINE

Atropine sulfate monohydrate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Minims Atropine Eye Drops contain atropine sulfate monohydrate 1% w/v. No preservatives are contained in the formulation.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

A single-use eye drops, solution.

Minims Atropine Eye Drops are clear, colourless sterile eye drops. No preservatives are contained in the formulation.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Minims Atropine Eye Drops are indicated to produce mydriasis and cycloplegia.

4.2 DOSE AND METHOD OF ADMINISTRATION

Adults (including the elderly):
One drop to be instilled into the eye, or as required.

Systemic absorption of atropine 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 naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.).

Each Minims Atropine Eye Drops unit should be discarded after a single use.

4.3 CONTRAINDICATIONS

Minims Atropine Eye Drops are contraindicated in patients with hypersensitivity to any of the components of the preparation.

Minims Atropine Eye Drops are contraindicated in the presence of angle closure glaucoma or where angle closure glaucoma is suspected.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Identified precautions

Minims Atropine Eye Drops are for topical ophthalmic use only. The solution should not be injected.

Due to the risk of precipitating an acute attack, atropine eye drops should not be used 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 be used.

Atropine eye drops should not be used in the following situations unless the clinical benefit outweighs the risk: keratoconus (atropine may produce fixed dilated pupil), synechiae between the iris and lens.

Due to the risk of provoking hyperpyrexia, atropine eye drops should be used with caution, especially in children, when the ambient temperature is high.

Persons with Down's syndrome appear to have an increased susceptibility to the actions of atropine, whereas those, with albinism may be resistant.

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Use in the elderly

Minims Atropine Eye Drops should be used with caution in elderly patients as they may be more susceptible to the effects of atropine thus increasing the potential for systemic side effects.

Paediatric use

Children may be more susceptible to the adverse effects of atropine. Therefore, atropine eye drops should be used with caution in this population. 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.

Atropine eye drops are not recommended in infants aged less than 3 months due to the possible association between induced cycloplegia and the development of amblyopia.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Although negligible Atropine passes into the bloodstream after ocular instillation, drug interactions are nevertheless possible.

The interactions observed with Atropine administered by any route should therefore be taken into account.

Anticholinergics: If significant systemic absorption of ophthalmic atropine occurs, concurrent use of other anticholinergics or medications with anticholinergic activity (eg. amantadine, some antihistamines, butyrophenones and phenothiazines, and tricyclic antidepressants) may result in potentiated anticholinergic effects.

Antiglaucoma agents: (Cholinergic, long acting, ophthalmic.) Concurrent use with atropine may antagonise the antiglaucoma and miotic actions of ophthalmic long acting cholinergic antiglaucoma agents. Concurrent use with atropine may also antagonise 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 anticholinergic 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; however, this counteraction may be used to therapeutic advantage.

Central nervous system 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

Effects on fertility

Studies have not been performed in either animals or humans to evaluate the potential fertility impairing effects of atropine.

Use in pregnancy – Pregnancy Category A

Atropine sulphate may be systemically absorbed after ocular administration; however, significant effects on the foetus have not been reported. Nevertheless, caution is advised.

Use in lactation.

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

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Minims Atropine Eye Drops may cause transient blurring of vision on instillation. Patients should be advised not to drive or operate hazardous machinery until vision is clear.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare

professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

Adverse effects rarely occur with ocular use of atropine, however, the following have been reported:

Ophthalmic: Blurred vision, local irritation, allergic conjunctivitis or blepharoconjunctivitis, contact dermatitis, eczematous dermatitis, increased intraocular pressure. May precipitate narrow angle glaucoma.

Systemic: Systemic reactions may occur after ocular instillation of these anticholinergic drugs, particularly in children or elderly patients. Symptoms of systemic toxicity include dryness of the mouth and skin, flushing, fever, rash, thirst, tachycardia, irritability, hyperactivity, ataxia, confusion, somnolence, hallucinations and delirium.

4.9 OVERDOSE

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

Systemic reactions to topical atropine are unlikely at normal doses. Signs of overdosage are similar to those described as systemic effects (see Section 4.8 Adverse Effects).

In the event of atropine overdose, treatment is supportive. Supportive therapy may include oxygen and assisted respiration; cool water baths for fever, especially in children; and catheterisation for urinary retention. In infants and small children, the body surface should be kept moist.

Diazepam may be given to control marked excitement and convulsions.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Atropine is a belladonna alkaloid. Atropine sulphate acts in the eye to block the action of acetylcholine, relaxing the cholinergically innervated sphincter muscles 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).

Atropine sulphate has a slower onset and more prolonged effect than most other anticholinergics. Maximum mydriatic effect occurs around 30 to 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.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

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.

Distribution

Atropine is rapidly cleared from the blood and is distributed throughout the body. It crosses the blood-brain barrier.

Metabolism

Atropine is incompletely metabolised in the liver. A half-life of four hours has been reported.

Excretion

Atropine is excreted in the urine as unchanged drug and metabolites.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Hydrochloric acid and purified water.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store at 2°C to 8°C. (Refrigerate. Do not freeze.). Protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER

Minims Atropine Eye Drops 1% (10 mg/mL) are supplied in a single use polypropylene tube (unit) overwrapped in a polyester/paper blister. The blisters are packed in cartons of 20 units. Each unit contains approximately 0.5 mL of solution.

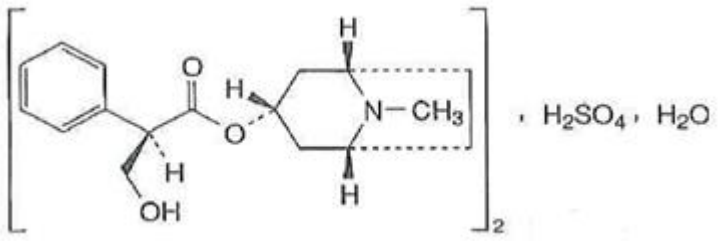
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Each Minims Atropine Eye Drops unit should be discarded after a single use.

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure



Chemical name: Bis[(1R,3r,5S)-8-methyl-8-azabicyclo[3.2.1]oct-3-yl (2*RS*)-3-hydroxy-2-phenylpropanoate] sulfate monohydrate

Molecular formula: $(C_{17}H_{23}NO_3)_2.H_2SO_4.H_20$

Molecular weight: 694.8

CAS number

5908-99-6

7 MEDICINE SCHEDULE (POISONS STANDARD)

S4 – Prescription Only Medicine

8 SPONSOR

Bausch & Lomb (Australia) Pty Ltd

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Chatswood, NSW 2067

9 DATE OF FIRST APPROVAL

11 March 2008

10 DATE OF REVISION

29 April 2020

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	New PI format
All	Active ingredient name change to align with name used internationally