SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

ATROPINE EYE DROPS, 10 mg/ml, Sterile eye drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each one ml contains atropine as atropine sulphate 10 mg.

Excipient with known effect: benzalkonium chloride 0,01 % *m/v* and boric acid 0,40 % *m/v.*

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Sterile eye drops

Clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

As a cycloplegic or mydriatic for refraction or for desired dilatation of the iris or uveal tract during inflammatory conditions.

4.2 Posology and method of administration

For uveitis

One drop three times daily.

For refraction

One drop in the eyes twice daily for one or two days before examination, and one hour before examination.

Pressure should be maintained over lacrimal sac, occluding lacrimal duct for one minute after instillation.

Method of administration

Topical

4.3 Contraindications

- Hypersensitivity to atropine or to any of the inactive ingredients of ATROPINE EYE DROPS listed in section 6.1.
- Not to be used in glaucoma or tendency towards glaucoma, and in persons hypersensitive to belladonna alkaloids.
- Should not be used by children under the age of six.

4.4 Special warnings and precautions for use

Administration of ATROPINE EYE DROPS may increase the intraocular pressure, especially in patients with a small anterior chamber or narrow anterior chamber angle. Before starting treatment, the intraocular pressure should be measured and the depth of the anterior chamber angle evaluated to avoid glaucoma attacks.

If eye pain occurs, discontinue, and see your doctor immediately, as this may indicate undiagnosed glaucoma.

Systemic exposure to ATROPINE EYE DROPS may cause central nervous system disorders (see section 4.8). Elderly patients are at increased risk of systemic adverse effects when using ATROPINE

EYE DROPS. Due to the risk of hyperthermia, the medicine should be used with caution in patients with fever or at increased ambient temperature.

Patients may develop increased photosensitivity and should protect their eyes from bright light (see section 4.8).

May only be used on prescription.

ATROPINE EYE DROPS contains benzalkonium chloride, which can cause eye irritation and has been found to discolour soft contact lenses. Contact with soft contact lenses should be avoided.

Patients should remove the contact lenses (soft or hard) before administering ATROPINE EYE DROPS and wait for at least 15 minutes before re-inserting them.

Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised.

Patients should be monitored in case of prolonged use.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

The effects of ATROPINE EYE DROPS may be potentiated by the concomitant administration of other products with antimuscarinic properties, e.g., some antihistamines and tricyclic antidepressants.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of ATROPINE EYE DROPS in pregnancy has not been established.

Breastfeeding

The safety of ATROPINE EYE DROPS in lactation has not been established.

Fertility

No human data available.

4.7 Effects on ability to drive and use machines

ATROPINE EYE DROPS has a major influence on the ability to drive and use machines.

ATROPINE EYE DROPS can cause drowsiness, blurred vision and sensitivity to light. Patients using ATROPINE EYE DROPS should not drive or perform dangerous activities until their vision clears.

4.8 Undesirable effects

Tabulated summary of adverse reactions

MedDRA System Organ Class	**Description and frequency**
Immune system disorders	*Not known:* Hypersensitivity
Psychiatric disorders	*Frequent:* Hallucinations, confusion, agitation
	Not known: Disorientation

Nervous system disorders	*Not known:* Vertigo, headache, ataxia, slurred speech, anxiety, hyperactivity, convulsions, inability to recognize people, sleepiness, dizziness
Eye disorders	*Frequent:* Photosensitivity, pain in the eye, visual disturbance
	Less frequent: closed-angle glaucoma
	Not known: Eyelid oedema, blurred vision, prolonged drug effect (mydriasis), conjunctivitis, hyperaemia, eye oedema and secretion
Cardiac disorders	*Frequent:* Tachycardia
	Not known: Bradycardia
Vascular disorders	*Not known:* Hypotension, vasodilation
Respiratory, thoracic and mediastinal disorders	*Not known:* Respiratory depression, decreased pharyngeal, bronchial and nasal secretion
Gastrointestinal disorders	*Frequent:* Constipation
	Not known: Ileus, bloating, vomiting, decreased gastrointestinal motility and decreased salivary gland secretion, dryness of the mouth
Skin and subcutaneous tissue disorders	*Not known:* Erythema, rash, decreased sweat gland secretion (dryness of the skin)
Renal and urinary disorders	*Not known:* Urinary retention
General disorders and administration site conditions	*Frequent:* Pyrexia and flushing

Description of selected adverse reactions

This medicine causes reactions similar to those of other anticholinergics. Adverse reactions from the central nervous system may occur: ataxia, slurred speech, anxiety, hallucinations, hyperactivity, convulsions, time and space disorientation, and inability to recognize people. Other signs of anticholinergic toxicity include skin rash, sleepiness, tachycardia, hyperpyrexia, vasodilatation, urinary retention, and decreased gastrointestinal motility, decreased salivary and sweat secretion, decreased secretion in the pharynx, bronchi and the nasal cavity. Severe reactions such as hypotension with rapidly progressive respiratory failure (respiratory depression) may occur.

Mydriatics may increase the intraocular pressure and induce a glaucoma attack in patients with a predisposition to acute narrow-angle glaucoma (see section 4.4).

Prolonged use of mydriatics may cause local irritation characterized by conjunctivitis (follicular), ocular hyperaemia, eye oedema, secretion and eczema.

Symptoms of toxicity are usually transient (several hours) but may last up to 24 hours.

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 providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Symptoms

Toxic doses cause tachycardia, rapid or stertorous respiration, hyperplexia, restlessness, confusion and excitement and hallucination passing into delirium. In severe intoxication depression of the central nervous system may occur with respiratory depression.

Treatment

Empty the stomach by aspiration and lavage. A saline purge should be given to promote peristalsis. Short acting barbiturates may be used for the state of excitement. Peripheral symptoms can be relieved by subcutaneous injection of neostigmine methyl sulphate 5 mg repeated at intervals.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 15.4 Ophthalmic preparations. Others.

Pharmacotherapeutic group: mydriatics and cycloplegics, ATC code: S01FA01

Atropine sulphate has parasympatholytic effects which include paralysis of ocular accommodation and dilatation of the pupil. Possible inflammation of the eyes significantly reduces its duration of action.

Atropine acts by blocking the cholinergic receptors in the sphincter of the pupil and the ciliary muscle.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium Chloride Solution 50 % *m/v*

Boric acid

Disodium Edetate

Hydrochloric Acid 32 % (2N solution) (for pH adjustment)

Sodium Carbonate Monohydrate

Sodium Chloride

Sodium Hydroxide (2N solution) (for pH adjustment)

Water for Injection

6.2 Incompatibilities

Not known

6.3 Shelf life

3 years

Do not use for more than 30 days after opening.

6.4 Special precautions for storage

Store at or below 25 °C. Protect from light and moisture.

Keep the dropper bottle tightly closed.

Discard 30 days after opening (see section 6.3).

6.5 Nature and contents of container

ATROPINE EYE DROPS are packed in 10 ml white dropper bottle with a natural/clear dropper insert and a maroon screw-on cap.

6.6 Special precautions for disposal and other handling

Do not use more than 30 days after opening (see section 6.4).

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand,

1685

Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER

J/15.4/312

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration: 06 December 1977

10. DATE OF REVISION OF THE TEXT

28 October 2022

Botswana: [S2] B9302845

Namibia: [NS2] 90/15.4/0097