

Summary of Product Characteristics

TROPIN 1%

1. Name of the medicinal product

TROPIN 1%

2. Qualitative and quantitative composition

Each 1 mL contains Atropine sulfate 10 mg
For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Eye drops, solution
Clear, colorless sterile ophthalmic solution

4. Clinical particulars

4.1 Therapeutic indications ^[1.1]

Atropine sulfate is an antimuscarinic agent used as a cycloplegic and mydriatic. The eye drops are used the treatment of iritis and uveitis to immobilise the iris and ciliary muscle and to prevent or break down adhesions.

Since it is a powerful cycloplegic it is used in the determination of refraction in children below six years and children with convergent strabismus.

4.2 Posology and method of administration ^[1.2]

The depth of the angle of the anterior chamber should be assessed before the product is used.

Posology

Adults

Refraction: One or two drops to be instilled into the eye(s) one hour before refracting.

Uveitis/iritis: One or two drops to be instilled into the eye(s) to a maximum of 4 times daily.

Elderly

Mydriatics and cycloplegics should only be used with caution in the elderly and others who may have raised intra ocular pressure.

Paediatric population

Refraction: One drop to be instilled into each eye twice daily for 1-3 days prior to the examination.

Uveitis/iritis: One drop to be instilled into each eye to a maximum of 3 times daily.

Method of administration

For topical ocular use.

Patients should be instructed to wash their hands before use and avoid allowing the tip of the container to come into contact with the eye or surrounding structures.

Patients should also be instructed that ocular solutions, if handled improperly, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

4.3 Contraindications ^[1.3]

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

The product should not be used in patients with closed angle glaucoma.

It is also contraindicated in patients with narrow angle between the iris and the cornea since it may raise intra-ocular pressure and precipitate an acute attack of closed angle glaucoma.

4.4 Special warnings and precautions for use ^[1.4]

It should only be used with caution in patients who may have raised intra ocular pressure.

Patients should be warned that antimuscarinic eye drops will temporarily impair vision.

Patients should wash hands after using the eye drops and great care should be taken to avoid getting the product into the mouth.

Due to the risk of provoking hyperpyrexia, atropine should only be used with great caution when the ambient temperature is high, or the patient has a fever.

Care is also required in patients with conditions characterised by tachycardia. Darkly pigmented iris is more resistant to pupillary dilation and caution should be exercised to avoid overdosage.

During use, care should be taken not to touch the dropper nozzle on to the eyelid or any other surface.

The product is for external use only and should be stored out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction ^[1.5]

The effects of atropine may be enhanced by the concomitant use of other drugs with antimuscarinic properties. Studies have indicated that the absorption of atropine sulphate appears to be delayed by solutions of higher osmolarity.

4.6 Fertility, pregnancy, and lactation ^[1.6]

Pregnancy

There are no or limited amount of data from the use of atropine in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of Tropin 1% during pregnancy.

Breast-feeding

It is unknown whether atropine or its metabolites are excreted in human milk. A risk to newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Tropin 1% therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility

There are no human data on the effect of atropine sulfate on male or female fertility.

4.7 Effects on ability to drive and use machines ^[1.7]

Tropin 1% may have a minor influence on the ability to drive and use machines. May cause transient blurring of vision instillation. Warn patients not to drive or operate hazardous machinery until vision is clear.

4.8 Undesirable effects ^[1.8]

Patients may experience photophobia and eyes should be protected from bright light while the pupils are dilated.

Prolonged use of atropine eye drops may lead to local irritation, transient stinging, hyperaemia, oedema and conjunctivitis. An increase in intra-ocular pressure may occur, especially in patients with closed angle glaucoma.

Hypersensitivity to atropine is not uncommon and may appear as a skin rash or conjunctivitis.

Systemic toxicity may be produced by the instillation of the eye drops especially in infants and the elderly. Reported symptoms include severe ataxia, restlessness, excitement and hallucinations.

Other adverse effects may include a dry mouth with difficulty in swallowing and talking, flushing and a dry skin, transient bradycardia followed by tachycardia, palpitations and arrhythmias, reduced bronchial secretions, urinary urgency and retention and constipation. Side effects that occur occasionally include confusion (particularly in the elderly), nausea, vomiting and giddiness.

4.9 Overdose ^[1.9]

Symptoms

Systemic reactions to topical atropine are unlikely at normal doses. Symptoms which can occur following an overdose, however, include anticholinergic effects (as listed in section 4.8 above), cardiovascular changes (tachycardia, atrial arrhythmias, atrioventricular dissociation) and central nervous system effects (confusion, ataxia, restlessness, hallucination, convulsions).

Treatment

Supportive therapy should be given as required.

5. Pharmacological properties

5.1 Pharmacodynamic properties ^[1.10]

Pharmacotherapeutic group: anticholinergics agents ATC code: S01FA01

Dilation of the pupil normally occurs within half an hour following local application and lasts for seven days or longer.

Paralysis of accommodation in one to three hours with recovery in three to seven days.

5.2 Pharmacokinetic properties ^[1.11]

Atropine is readily absorbed from the gastro-intestinal tract and mucous membranes, it is also absorbed from the eye.

It is incompletely metabolised in the liver and is excreted in the urine as unchanged drug and metabolites.

5.3 Preclinical safety data ^[1.12]

No additional pre-clinical data of relevance to the prescriber.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium chloride

Boric acid

Hypromellose

Hydrochloric acid

Sodium hydroxide

Water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30°C.

Discard 24 hours after opening.

6.5 Nature and contents of container

LDPE plastic tube 0.3 and 0.5 mL packed in aluminium sachet of 10 tubes and packed in paper box of 3 sachets.

7. Marketing authorization holder

Millimed BFS Co., Ltd.

174, 179 Moo 8, Pha Ngam, Wiang Chai,

Chiang Rai, 57210, Thailand.

Tel. 0 2945 9555

8. Marketing authorization number(s)

1A 106/67

9. Date of first authorization/renewal of the authorization

27 October 2024

10. Date of revision of the text

2 October 2024