SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Atropine Eye Drops 1.0% w/v

Vistatropine Eye Drops 1.0% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Atropine sulfate 1.0% w/v

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops.
Clear, colourless, solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Atropine sulfate is an antimuscarinic agent used as a cycloplegic and mydriatic. The eye drops are used in 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

For topical ocular use.

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

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

Children

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.

4.3 Contraindications

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.

It should not be used by patients with known hypersensitivity to any component of the preparation.

4.4 Special warnings and precautions for use

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

The product contains benzalkonium chloride solution and soft contact lenses must not be worn during the period of use.

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.

The eye drops should be discarded 4 weeks after first opening.

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

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

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

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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

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, atrio-ventricular 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

Pharmacotherapeutic group: anticholinergic 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

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

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

6 PHARMACEUTICAL PARTICULARS

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6.1 List of excipients

Benzalkonium chloride solution

Purified water

6.2 Incompatibilities

None known relevant to topical ocular use.

6.3 Shelf life

36 months (unopened)
28 days (once opened)

6.4 Special precautions for storage

Store bottle upright below 25°C in a dry place and protect from light.

6.5 Nature and contents of container

Low density polythene 10ml bottle with polythene insert and high density polythene tamper-evident cap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Martindale Pharmaceuticals Ltd,
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Harold Hill,
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8. MARKETING AUTHORISATION NUMBER

PL 00156 / 0044

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First authorised: 6 June 1997

10 DATE OF REVISION OF THE TEXT

06/10/2016