Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minims Atropine Sulphate 1% Eye Drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Atropine Sulphate 1% w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution
Single use, clear, colourless, sterile solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Minims Atropine Sulphate is indicated:

As a mydriatic and cycloplegic agent.
For pre-operative use in ophthalmic surgery.
For treatment of uveitis and refraction.

4.2 Posology and method of administration

Adults (including the elderly)

Uveitis: 1 drop 2-3 times a day.

Refraction: 1 drop twice a day prior to examination.

4.3 Contraindications

Use in patients with a known hypersensitivity to atropine.

Due to the risk of precipitating an acute attack, do not use 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 is used.

4.4 Special warnings and precautions for use

This product should be used with caution in an inflamed eye, as hyperaemia greatly increases the rate of systematic absorption through the conjunctiva.

Systemic absorption 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.)

4.5 Interaction with other medicinal products and other forms of interactions

None known

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

Transient stinging may occur on installation.

Side effects include local irritation, hyperaemia, oedema and conjunctivitis, especially with repeated administration.

Side effects rarely occur but include anticholinergic effects such as dry mouth and skin, flushing, increased body temperature, urinary symptoms, gastrointestinal symptoms and tachycardia. These effects are more likely to occur in infants and children.

4.9 Overdose

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 is supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Atropine sulphate is a competitive antagonist of acetylcholine at postganglionic cholinergic (parasympathetic) nerve endings.

Atropine does not discriminate between the recently discovered muscarinic receptor sub types M1 (in parasympathetic ganglia of the submucous plexus, with high affinity for selecting antimuscarinic pirenzepine) and M2 (low affinity for pirenzepine and occurring predominantly in heart and smooth muscle.

5.2 Pharmacokinetic properties

Atropine is well absorbed from the small bowel and not at all from the stomach. Thus the effects of oral dosing are much slower in onset than after parenteral dosing. Atropine is also absorbed by mucous membranes but less readily from the eye and skin, although significant toxicity can sometimes occur through absorption of excessive eye drops.

Atropine has a volume of distribution of 1-6 l/kg. Protein binding is moderate, with approximately 50% of the drug bound in plasma. Its plasma clearance is 8ml/min/kg.

Only traces of atropine are found in breast milk. The drug readily crosses the blood-brain barrier and may cause confusion and delirium post-operatively. It crosses the placenta readily.

Atropine is metabolised by hepatic oxidation and conjugation to inactive metabolites, with about 2% undergoing hydrolysis to tropine and tropic acid. About 30% of the dose is excreted unchanged in the urine. Only trace amounts of the dose are eliminated in the faeces.

There is some evidence of prolonged elimination in elderly subjects.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid (for pH adjustment)
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

15 months
Each Minims unit should be discarded after a single use.

6.4 Special precautions for storage

Store below 25^{o}C. Do not freeze. Store in the original container.

6.5 Nature and contents of container

A sealed conical shaped container fitted with a twist and pull off cap made from Ph. Eur. Grade polypropylene for containers and closures for parenteral and ophthalmic preparations. Each Minims unit is overwrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5ml of solution. Each carton contains 20 Minims units.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For single use only. Discard any remaining solution.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA23259/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 1st April 2009

10 DATE OF REVISION OF THE TEXT

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