SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Atropine Sulphate 1% w/v eye drops solution in single dose container

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Preservative Free (PF), clear, colourless, sterile eye drops containing Atropine Sulphate PhEur 1% w/v.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Sterile, single-use eye drops.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As a topical mydriatic and cycloplegic

4.2 Posology and method of administration

Adults (including the elderly):

One drop to be instilled into the eye, or as required.

4.3 Contraindications

Hypersensitivity to any component of the preparation.

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

The protracted mydriasis which is difficult to reverse, may be a disadvantage.

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.)

Excipient(s)

Sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium- free'.

4.5 Interaction with other medicinal products and other forms of interaction

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

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.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

Pharmacotherapeutic group: anticholinergic agents

ATC code: S01FA01

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 Ml (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
Sodium hydroxide for pH adjustment
Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

After first opening of the sachet: keep the single-dose containers in their sachet in order to protect from light and use them within 30 days.

After opening of the single-dose container: discard any residual solution remained in the single dose container after instillation.

6.4 Special precautions for storage

Store below 25°C. Do not freeze.

Keep the single-dose containers in their sachet in order to protect from light and use them within 30 days.

For storage conditions after first opening of the single-dose container, see section 6.3.

6.5 Nature and contents of container

Atropine sulfate 1% w/v eye drops solution is available in low density polyethylene single-dose units, containing 0.5 ml solution each.
Each strip of 5 single dose containers is packed in a PET/Alu/PE sachet.
The box contains 20 single dose containers.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

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10. DATE OF REVISION OF THE TEXT

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