ASHFORD LABORATORIES LIMITED

SUMMARY OF PRODUCT CHARACTERISTICS

1-Name of the Medicinal Product:

1.1 Product Name: ATROPINE Eye Drops
(Atropine Sulfate Ophthalmic Solution USP)

1.2 Strength: 1%

1.3 Pharmaceutical Dosage Form: Ophthalmic Solution (Eye Drops)

2-Quality and Quantitative Composition:

Each mL contains: Atropine Sulfate ..... 10 mg

3-Pharmaceutical Form: Ophthalmic solution (Eye Drops)

4-Clinical Particulars

4.1 Therapeutic indications:

ATROPINE Eye Drops is indicated to dilate the pupil and paralyze accommodation when carrying out objective determination of refraction (especially in children), treatment of children suffering from strabismus (amblyopia) and inflammation of the anterior segment (keratitis or cornea ulcers associated with irritation of the iris).

4.2 Posology and method of administration:

Instill 1 – 2 drops two to three times a day in the lower fornix of the conjunctiva.

4.3 Contraindications:

Atropine Sulfate is contraindicated in patients with glaucoma or a tendency to glaucoma, e.g. narrow anterior chamber angle.

4.4 Special warning and precautions for use:

Atropine Sulfate occasionally causes local irritation of the eye and may produce swelling of the eyelids and conjunctivitis on susceptible persons. Continuous use of the drug may cause chronic conjunctivitis. Cease usage if adverse reactions persist and consult your doctor.

4.5 Interaction with other medicinal products and other forms of interactions:

Specific drug interaction studies have not been conducted.

4.6 Pregnancy and Lactation There are no adequate and well controlled studies in pregnant women:

Safety for use in pregnancy has not been established.

4.7 Effects of the ability to drive and use machines:
None known

4.8 Undesirable Effects:
Atropine Sulfate occasionally causes local irritation of the eye and may produce swelling of the eyelids and conjunctivitis on susceptible persons. Continuous use of the drug may cause chronic conjunctivitis. Cease usage if adverse reactions persist and consult your doctor.

4.9 Overdose and special antidotes:
None known

5-Pharmacological Properties :

Atropine is used as a cycloplegic and mydriatic. Dilatation of the pupil occurs in half an hour following one local application and lasts for a week or more; marked paralysis of accommodation is obtained in 1 to 3 hours with recovery in 3 to 7 days. It is used in the treatment of iritis and uveitis to immobilize the ciliary muscle and iris to prevent or break down adhesions. Because of its powerful cycloplegic action atropine is also used in determination of refraction in children below the age of 6 and in children with convergent strabismus. In the treatment of inflammatory eye disorders such as uveitis and iritis, the dose of atropine sulfate for adults is 1 to 2 drops of a 0.5% or 1.0% solution instilled into the eye(s) up to four times daily. The dose in children is 1 to 2 drops of a 0.5% solution (or one drop of a 1.0% solution) instilled up to three times daily. For refraction in adults the dose is one drop of a 1% solution of atropine sulfate; this may be instilled either twice daily for 1 to 2 days before the procedure or on a single occasion one hour before the procedure. In children the dose for refraction is 1 to 2 drops of a 0.5% (or one drop of a 1% solution) instilled twice daily for 1 to 3 days before the procedure, with a further dose given before the procedure.

Atropine solution may be used as oily eye-drops, or the sulfate or methonitrate may be used in aqueous eye-drops or eye ointments. In some patients atropine may cause conjunctival irritation and for this lachesine chloride may provide a suitable alternative.

Atropine has been used in the form of liniment or belladonna plaster to relieve the pain of muscular rheumatism, sciatica, and neuralgia although there is no rationale for such usage.

PHARMACOKINETICS

Atropine is readily absorbed from the gastro-intestinal tract; it is also absorbed from mucous membranes, the eye, and to some extent through intact skin.

It is rapidly cleared from the blood and is distributed throughout the body. It crosses the blood-brain barrier. It is incompletely metabolized in the liver and is excreted in the urine as unchanged drug and metabolites. A half-life of about 4 hours has been

reported. Atropine crosses the placenta and traces appear in milk.

Quartenary ammonium salts of atropine, such as methonitrate, are less absorbed by mouth. They are highly ionized in body fluids and being poorly soluble in lipids they do not readily cross the blood-brain barrier.

Ref.: MARTINDALE – The Extra Pharmacopoeia, 31st edition.

6-Pharmaceutical Particulars :

6.1 List of excipients

1. Sodium Chloride USP
2. Boric Acid NF
3. Sodium Metabisulfite NF
4. Disodium Edetate USP
5. Benzalkonium Chloride 50 % Solution NF
6. Purified Water USP

6.2 Incompatibilities : None

6.3 Shelf life :

a.) As packages for sale: **3 years**
b.) After first opening: **Discard 4 weeks from opening**

6.4 Special precautions for storage: Store at temperature 20°C – 25°C.

6.5 Nature and contents of container :

10 mL, packed in LDPE clear bottle and plug with HDPE red cap

7-Marketing Authorization Holder : **Linkabs Pharmaceuticals Ltd.**

8-Marketing Authorization Numbers : **04-3886**

9-Date of first authorization/renewal of the authorization : **10 September 2019**

10-Date of revision of the text : --