ASHFORD LABORATORIES LIMITED

SUMMARY OF PRODUCT CHARACTERISTICS

1-Name of the Medicinal Product :

1.1 Product Name : **ALLEREX Eye Drops**
(Antazoline Hydrochloride & Tetrahydrozoline Hydrochloride Ophthalmic Solution)

1.2 Strength: 0.05% & 0.04%

1.3 Pharmaceutical Dosage Form: Ophthalmic Solution (Eye Drops)

2-Quality and Quantitative Composition :

Each mL contains:	Antazoline HCl	0.5 mg
	Tetrahydrozoline HCl	0.4 mg

3-Pharmaceutical Form : Ophthalmic solution

4-Clinical Particulars

4.1 Therapeutic indications:
ALLEREX Eye Drops is indicated in the treatment of irritant conjunctivitis, allergic inflammatory conditions of the conjunctiva, particularly hay fever conjunctivitis and vernal conjunctivitis.

4.2 Posology and method of administration:
In the acute stage, 1 drop every three hours; for continuous use, 1 drop 2-3 times daily is sufficient. In severe cases, Allerex can be used as frequently as 1 drop once an hour without any side effects being observed. In the case of infants, not more than 1-2 drops should be administered daily.

4.3 Contraindications:
Hypersensitivity to any of its components. Narrow-angle glaucoma is a contraindication of this eye drops.

4.4 Special warning and precautions for use:
Avoid use while wearing contact lenses. Patients with cardiovascular disease, diabetes, hypertension, prostatic enlargement and thyroid disease should use with caution.

4.5 Interaction with other medicinal products and other forms of interactions:
Monoamine oxidase inhibitors (MAOI) have been reported to cause an increase in the alpha-adrenergic effects, such as causing hypertension of sympathomimetic drugs.

4.6 Pregnancy and Lactation There are no adequate and well

controlled studies in pregnant women:
No studies have been carried out on the use of Allerex in pregnancy and lactation and for infants. Use in pregnancy should be under physician's instruction.

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

4.8 Undesirable Effects:
A mild burning sensation may occur for a short time directly after instillation of the eye drops. Headache, sleepiness and tachycardia may occur in isolated cases. Hypersensitivity to the ingredients, in particular to antazoline, may occur in very rare cases. Some systemic reactions, such as gastrointestinal reactions, muscular tremor and palpitation may occur. This eye drops may cause stinging, burning and reactive hyperemia especially in prolonged use.

4.9 Overdose and special antidotes:
None known

5-Pharmacological Properties:

Tetrahydrozoline Hydrochloride is a sympathomimetic agent with marked alpha-adrenergic activity. It is a vasoconstrictor and when applied topically to mucous membranes it reduces swelling and congestion.

It is used for the symptomatic relief of nasal congestion. A 0.1% solution is instilled into each nostrils as nasal drops of spray three to four times daily as necessary; it should not be used more often than 3 hours. Children aged 2 to 6 years of age maybe given 2 to 3 drops of a 0.05% solution

Solution of tetrahydrozoline hydrochloride containing 0.05% are used as a conjunctival decongestant.

Ref.: Martindale 31st edition, p. 1593

Antazoline, an ethylenediamine derivative, is an antihistamine used for the treatment of rhinitis and conjunctivitis. It is used as the hydrochloride, phosphate, or sulphate in the nose drops and eye drops, most commonly in a concentration of 0.5%; the mesylate has also been used. Antazoline salts are often used as a vasoconstrictor such as naphazoline hydrocloride or nitrate or xylometazoline hydrochloride.

Antazoline Hydrochloride is a sympathomimetic agent which is useful in controlling nasal itching, sneezing, rhinorrhoea, and ocular symptoms such as conjunctivitis, but is less effective for nasal congestion

Most antihistamines like antazoline hydrochloride are generally unsuitable for topical use in the nose or eye; they lack potency at the reduced dosage required for local

therapy, also there is the potential for sensitisation. However, some antihistamines such as antazoline salts and levocabastine have been applied topically to the nose and eye for control of symptoms.

Sympathomimetics cause vasoconstriction of capillaries in the nasal mucosa and are therefore used as nasal decongestants. They are useful in allergic rhinitis and may provide some benefit in perennial non-allergic rhinitis. They are also administered to the eye to relieve symptoms of allergic conjunctivitis.

PHARMACOKINETICS

Systemic absorption may follow topical administration of solutions of tetrahydrozoline. It is not used systemically, but is readily absorbed from gastro-intestinal tract.

Ref.: Martindale 31st edition, p. 1593

6-Pharmaceutical Particulars:

6.1 List of excipients

1. Hypromellose 2910 USP
2. Boric Acid NF
3. Sodium Borate 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 $20^{o}C - 25^{o}C$.

6.5 Nature and contents of container :

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

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

8-Marketing Authorization Numbers : **04-3534**

9-Date of first authorization/renewal of the authorization : **25 February 2020**

10-Date of revision of the text : --