IRISH MEDICINES BOARD ACT 1995, as amended

Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended

PA0148/016/001
Case No: 2077287

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Allergan Pharmaceuticals Ireland

Castlebar Road, **Westport**, **Co. Mayo**, **Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

ALBALON 1 mg/ml Liquifilm Eye Drops Solution

the particulars of which are set out in the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **25/08/2010**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

ALBALON 1 mg/ml Liquifilm Eye Drops Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Naphazoline hydrochloride 1mg/ml (0.1% w/v)

Excipients: contains Benzalkonium chloride 0.04mg/ml (0.004% w/v)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.
Clear, colourless to straw-coloured sterile solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

ALBALON is indicated for use as a topical ocular vasoconstrictor.

4.2 Posology and method of administration

Adults only: the usual dose is one or two drops 3 to 4 hours or as instructed by the physician.

Method of Administration: topical into the conjunctival sac (the head should be tilted back and the lower eyelid depressed to form a pocket, for instillation). As with any eye drops, to reduce possible systemic absorption, it is recommended that the lachrymal sac be compressed at the medial canthus (punctual occlusion) for one minute. This should be performed immediately following the instillation of each drop.

4.3 Contraindications

Use in patients with a known hypersensitive to naphazoline hydrochloride or any ingredient in the product.

This product should not be used in patients with narrow angle glaucoma or in the presence of an anatomically narrow angle.

Use in patients taking monoamine oxidase inhibitors or within 14 days of stopping such medication.

Naphazoline hydrochloride should not be used in infants under two years old.

4.4 Special warnings and precautions for use

Use with caution on an inflamed eye, as hyperaemia greatly increases the rate of systemic absorption through the conjunctiva and prolonged or frequent use, especially in an inflamed eye, may result in increased absorption and possible systemic effects.

The puncta should be depressed after instillation of drops to reduce drainage through the nasolacrimal duct to the oral and nasal mucosa (see section 4.2).

CNS depression leading to coma and marked reduction in body temperature may occur in children especially infants.

Use with care in patients suffering from cardiovascular disease, hypertension, diabetes or hyperthyroidism.

If red eye persists, further consultation should be undertaken.

The preservative in ALBALON, benzalkonium chloride, may cause eye irritation. Avoid contact with soft contact lenses. The contact lenses should be removed prior to application and reinserted after at least 15 minutes. Benzalkonium chloride is known to discolour soft contact lenses.

4.5 Interaction with other medicinal products and other forms of interaction

Decongestants may increase the activity of:
Tricyclic antidepressants.

Concurrent use of maprotiline or tricyclic antidepressants and naphazoline may potentiate the pressor effect of naphazoline.

A severe hypertensive crisis may ensue in patients under MAO inhibitor medication from use of a sympathomimetic drug (see section 4.3).

Decongestants may decrease the activity of:
Analgesics
Anticholinesterases

4.6 Pregnancy and lactation

Pregnancy:
There are no adequate experimental studies in animals for identifying a potential impact on pregnancy, embryonic development, foetal development or postnatal development. The potential risk for humans is (therefore) not known. ALBALON should not be used during Pregnancy, unless it is clearly necessary.

Lactation:
It is unknown whether naphazoline is secreted in breast milk. Therefore ALBALON should not be used during lactation.

4.7 Effects on ability to drive and use machines

ALBALON may cause dizziness, fatigue and/or drowsiness which may impair the ability to drive or operate machinery.

ALBALON may cause blurred and/or abnormal vision which may also impair the ability to drive or to use machinery, especially at night or in reduced lighting. The patient should wait until these symptoms have cleared before driving or using machinery.

4.8 Undesirable effects

Metabolism and Nutrition Disorders:
Not known: Hyperglycaemia

Nervous System Disorders:
Not known: Somnolence, Dizziness, Weakness, Headache, Nervousness

Eye Disorders:
Not known: Intraocular pressure increased, Punctate keratitis, Blurring, Mydriasis, Allergy, Lacrimation increased, Eye pain, Eye irritation, Ocular hyperaemia

Cardiac Disorders:

Not known: Arrhythmia

Vascular Disorders:
Not known: Hypertension

Gastrointestinal Disorders:
Not known: Nausea

General Disorders and Administration Site Conditions:
Not known: Hyperhidrosis

4.9 Overdose

Accidental ingestion (especially in children) may cause marked sedation requiring emergency treatment.

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Sympathomimetics used as decongestants.

ATC code: SOIGA 01

5.1 Pharmacodynamic properties

ALBALON is indicated for use as a topical ocular vasoconstrictor. The potent vasoconstrictive action of ALBALON is provided by naphazoline hydrochloride, a drug belonging to the imidazoline class of sympathomimetics. This active ingredient is a well-known and established compound, having been synthesized in 1940. It is currently used as a vasoconstrictor in several medicaments. Naphazoline hydrochloride constricts the vascular system of the conjunctiva. It is presumed this effect is due to direct action of the drug upon the alpha (excitatory) receptors of the vascular smooth muscle. Naphazoline is characterized by a relatively long duration of action; one drop of ALBALON brings more than three hours of effective decongestant activity, even to eyes with repeated insult. This characteristic of ALBALON is especially helpful for those living in an area with constant irritants such as pollution and dust.

5.2 Pharmacokinetic properties

Refer to 5.1.

5.3 Preclinical safety data

No relevant preclinical data are known for the application of ALBALON.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Poly(vinyl alcohol)
Disodium edetate
Sodium chloride
Sodium citrate dihydrate
Citric acid monohydrate
Benzalkonium chloride
Sodium hydroxide (for pH adjustment)
Purified water

6.2 Incompatibilities

Refer to section 4.4

6.3 Shelf Life

Shelf life: 3 years
In-use shelf life: Unused contents should be discarded within 28 days of first opening.

6.4 Special precautions for storage

Do not store above 25°C.

Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container

The product will be marketed as a sterile solution in a 15 ml size bottle with dropper applicator. All bottles and tips are made from low density polyethylene. The caps are made of polystyrene. A safety seal is placed around the bottle cap to ensure integrity of the product.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Allergan Pharmaceuticals Ireland
Castlebar Road
Westport
County Mayo

8 MARKETING AUTHORISATION NUMBER

PA 148/16/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st November 1982

Date of last renewal: 1st November 2007

10 DATE OF REVISION OF THE TEXT

August 2010