IRISH MEDICINES BOARD ACT 1995, as amended

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

PA0290/063/002
Case No: 2080568

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

Alcon Laboratories (UK) Ltd

Pentagon Park, **Boundary Way**, **Hemel Hempstead**, **Hertfordshire HP2 7UD**, **England**

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

Alomide Allergy 0.1% w/v 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 **06/07/2010**.

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

Alomide Allergy 0.1% w/v Eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains 0.1% w/v lodoxamide as lodoxamide trometamol.

Excipient: contains 0.007% w/v benzalkonium chloride as benzalkonium chloride solution.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution (eye drops).
A clear colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Alomide is indicated in the treatment of the ocular signs and symptoms of allergic conjunctivitis.

4.2 Posology and method of administration

Adults and children (4 years and above): One or two drops in each eye four times a day at regular intervals.

Alomide therapy is dependent upon its administration at regular intervals, as directed.

Alomide therapy should not be used for more than 4 weeks without seeking medical advice.
Improvements in signs and symptoms in response to Alomide therapy (decreased discomfort, itching, foreign body sensation, photophobia, acute ocular pain, tearing, discharge, erythema/swelling, conjunctival redness, limbal reaction, epithelial disease, ptosis) are usually evident within a few days, but longer treatment for up to four weeks is sometimes required. Once symptomatic improvement has been established, therapy should be continued for as long as needed to sustain improvement.

Instillation of eye drops in allergic conjunctivitis may cause discomfort initially; this will decline with improvement of the disease (see 4.8 Undesirable Effects).

Children less than 4 years: The safety and effectiveness of Alomide in children below the age of four years have not been established.

Elderly: There are no special precautions to be followed in prescribing Alomide for the elderly.

If required, corticosteroids may be used concomitantly with Alomide.

4.3 Contraindications

Alomide is contraindicated in those persons who have a known hypersensitivity to lodoxamide or any component of the

medicament.

4.4 Special warnings and precautions for use

Alomide is not for injection. The recommended frequency of administration should not be exceeded. As with all preparations containing benzalkonium chloride, users of soft (hydrophilic) contact lenses should refrain from wearing lenses while under treatment with Alomide. Lenses may be worn within a few hours of discontinuation of treatment.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Reproduction studies with lodoxamide trometamol administered orally to rats and rabbits in doses of 100 mg/kg/day (more than 5000 times the proposed human dose) produced no evidence of developmental toxicity. However, there are no adequate and well-controlled studies in pregnant women. Since animal reproduction studies are not always predictive of human response, Alomide should be used during pregnancy only if clearly needed.

It is not known whether lodoxamide is secreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Alomide is administered to nursing mothers.

4.7 Effects on ability to drive and use machines

Alomide is unlikely to affect a user’s ability to drive or to use machinery.

4.8 Undesirable effects

During clinical studies of Alomide, the most frequently reported ocular adverse experiences were transient burning, stinging, or discomfort upon instillation, which occurred in 13% of patients. Other ocular events occurring in 1 to 5% of the patients included ocular pruritus, blurred vision, lid margin crusting, dry eye, tearing and hyperaemia. Events that occurred in less than 1% of the patients included foreign body sensation, ocular pain, discharge, ocular oedema, ocular fatigue, ocular warming sensation, lid oedema, chemosis, anterior chamber cells, epitheliopathy, keratopathy/keratitis, blepharitis, sticky sensation, corneal erosion, dim vision, corneal abrasion and allergy. Non-ocular events are rare and reported at incidences below 1%; these included warm sensation, headache, nausea, stomach discomfort, dizziness, somnolence, dry nose, sneezing and rash.

4.9 Overdose

In the event of a topical overdose, flush from the eye with running water. Accidental overdose of an oral preparation of 120 to 180 mg of lodoxamide resulted in temporary sensation of warmth, profuse sweating, diarrhoea, light-headedness and a feeling of stomach distension; no permanent adverse effects were observed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Lodoxamide, a mast cell stabiliser inhibits the *in vivo* Type I immediate hypersensitivity reaction in animals and man.

In vitro studies have demonstrated the ability of lodoxamide to stabilise mast cells and prevent the antigen specific induced release of histamine. In addition, lodoxamide prevents the release of other mast cell inflammatory mediators (i.e. SRS-A, slow reacting substances of anaphylaxis also known as the peptido-leukotrienes). Lodoxamide inhibits histamine release *in vitro* by preventing the movement of calcium into the mast cell after stimulation.

5.2 Pharmacokinetic properties

The oral bioavailability of ^{14}C-lodoxamide in man is 71%, approximately 87% of the absorbed drug undergoes bio transformation. The metabolic transformation of lodoxamide results from stepwise hydrolysis of the oxylamide groups to form the monoxamate and the diamine. The diamine undergoes further hydroxylation followed by conjugation to either the O-glucuronide or O-sulphate. The O-glucuronide and O-sulphate metabolites account for 79% of the biotransformed lodoxamide, with the monoxamate and diamine accounting for 5% and 3% of the excreted metabolites. Only 2.7% of the absorbed dose is recovered as unchanged drug in the urine.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Mannitol (E421)
Hypromellose
Sodium citrate dihydrate
Citric acid monohydrate
Disodium edetate
Tyloxapol
Sodium hydroxide (for pH adjustment)
Hydrochloric acid concentrated (for pH adjustment)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened: 2 years.
Once opened: Discard four weeks after first opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Low-density polyethylene DROP-TAINER® bottle containing 5 ml of solution with low density polyethylene dispensing plug and tamper evident polypropylene screw cap.

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

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Alcon Laboratories (UK) Ltd
Pentagon Park
Boundary Way
Hemel Hempstead
Hertfordshire
HP2 7UD
England

8 MARKETING AUTHORISATION NUMBER

PA 290/63/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 03 June 2003
Date of last renewal: 03 june 2008

10 DATE OF REVISION OF THE TEXT

July 2010