Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Alomide 0.1% w/v Eye Drops, Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Alomide contains 0.1 % w/v Lodoxamide (as lodoxamide trometamol).
Excipients: Benzalkonium chloride 0.007% w/v

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

ALOMIDE Ophthalmic Solution is indicated in the treatment of non-infectious allergic conjunctivitis (vernal conjunctivitis, giant papillary conjunctivitis, and allergic-atopic conjunctivitis). The etiologic factors are unknown, but common airborne allergens and contact lenses have been implicated. Lodoxamide trometamol may be effective against other ocular diseases where type I immediate hypersensitivity (or mast cells) play a major role in the inflammatory process.

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.

Patients should be advised that the effect of ALOMIDE therapy is dependent upon its administration at regular intervals, as directed.

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.

Patients should also be advised that instillation of eye drops in allergic conjunctivitis may cause discomfort initially and that this will decline with improvement of the disease (see 4.8 Undesirable Effects).
Nasolacrimal occlusion or gently closing the eyelid after administration is recommended. This may reduce the systemic absorption of medicinal products administered via the ocular route and result in a decrease in systemic adverse reactions.

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 of the excipients.

4.4 Special warnings and precautions for use

- ALOMIDE is not for injection.
- The recommended frequency of administration should not be exceeded.
- Patients should be advised that instillation of eye drops may initially cause discomfort or transient burning or stinging (see section 4.8). Should these symptoms persist, the patient should be advised to contact the prescribing physician.
- ALOMIDE contains benzalkonium chloride, a preservative that may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. Patients must be instructed to remove contact lenses prior to application of ALOMIDE and wait at least 15 minutes before reinsertion.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

If more than one topical ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart. Eye ointments should be administered last.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of ALOMIDE in pregnant-women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of ALOMIDE during pregnancy.

Lactation
It is not known whether lodoxamide is excreted in human milk. There is insufficient information on the excretion of lodoxamide from ALOMIDE in animal milk. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from ALOMIDE therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

4.7 Effects on ability to drive and use machines

Lodoxamide has no or negligible influence on the ability to drive and use machines. As with any topical ophthalmic medicinal product, temporary blurred vision or other visual disturbances may affect the ability to drive or use the machines. If blurred vision or visual disturbances occur, the patient must wait until the vision is clear before driving or using machinery.

4.8 Undesirable effects

a. Summary of the safety profile
In clinical trials, the most common adverse reaction was ocular discomfort.

b. Tabulated list of adverse reactions
The following adverse reactions are classified according to the following convention: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), or not known (cannot be estimated from the available data). Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness. The adverse reactions have been observed during clinical trials and post-marketing experience for lodoxamide eye drops.

System Organ Classification	MedDRA Preferred Term (v.12.1)
Nervous system disorders	*Uncommon*: dizziness, headache *Rare*: somnolence, dysgeusia
Eye disorders	*Very common:* ocular discomfort *Common*: vision blurred, dry eye, eye pruritus, lacrimation increased, ocular hyperaemia *Uncommon*: eye pain, eye oedema, asthenopia (eye strain), corneal deposits, conjunctival oedema, abnormal sensation in eye, foreign body sensation in eyes, eye discharge, eye irritation *Rare:* corneal erosion, corneal scar, corneal abrasion, anterior chamber cell, corneal epithelium defect, keratitis, blepharitis, eye allergy, visual impairment, eyelid oedema, conjunctival disorder
Cardiac disorders	*Not known:* palpitations
Respiratory, thoracic and mediastinal disorders	*Rare*: nasal dryness, sneezing
Gastrointestinal disorders	*Uncommon*: nausea *Rare*: abdominal discomfort
Skin and subcutaneous tissue disorders	*Uncommon:* eyelid exfoliation *Rare*: rash
General disorders and administration site conditions	*Uncommon:* feeling hot

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Due to the characteristics of this preparation, no toxic effects are to be expected with an ocular overdose of this product.

In the event of a topical overdose, flush from the eye with lukewarm water.

In case of accidental ingestion of doses of 0.1 mg to 10.0 mg of lodoxamide, the following side adverse effects may occur: feeling of warmth, flushing, nausea, vomiting, diaphoresis and abdominal cramping. Transient elevations of systolic and diastolic blood pressure have been noted with doses of 3.0 and 10.0 mg of oral lodoxamide, but they resolve spontaneously after a short time. Other possible adverse effects after an oral overdose are: headache, dizziness, fatigue and loose stools.

If accidentally ingested, efforts to decrease further absorption may be appropriate.

Lavage, if the overdose has been taken within 1 hour or treatment with activated charcoal should be considered.

Treatment of any suspected ingestion is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Ophthalmologicals: Antiallergies
ATC Code: SO1G X05

Lodoxamide trometamol is a mast cell stabiliser that inhibits the *in vivo* Type I immediate hypersensitivity reaction. Lodoxamide inhibits the increases in cutaneous vascular permeability that are associated with reagin or IgE and antigen-medicated reactions.

In vitro studies have demonstrated the ability of lodoxamide to stabilise rodent mast cells and prevent antigen-stimulated 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) and inhibits eosinophil chemotaxis. Although lodoxamide's precise mechanism of action is unknown, the drug has been reported to prevent calcium influx into mast cells upon antigen stimulation.

Lodoxamide has no intrinsic vasoconstrictor, antihistaminic, cyclooxygenase inhibition or other anti-inflammatory activity.

5.2 Pharmacokinetic properties

The disposition of ^{14}C-lodoxamide was studied in six healthy adult volunteers receiving a 3 mg (50 µCi) oral dose of lodoxamide. Urinary excretion was the major route of elimination (83%). The elimination half-life of ^{14}C-lodoxamide was estimated from urinary excretion data to be 8.5 hours. In a study conducted in twelve healthy adult volunteers, topical administration of ALOMIDE, one drop in each eye four times per day for ten days, did not result in measurable lodoxamide plasma levels at a detection limit of 2.5 ng/mL.

5.3 Preclinical safety data

A long-term study with lodoxamide trometamol in rats (two-year oral administration) showed no neoplastic or tumorigenic effects at doses 100 mg/kg/day (more than 5000 times the proposed human clinical dose). No evidence of mutagenicity or genetic damage was seen in the Ames Salmonella Assay, Chromosomal Aberration in CHO Cells Assay, or Mouse Forward Lymphoma Assay. In the BALB/c-3T3 Cells Transformation Assay, some increase in the number of transformed foci was seen at high concentrations (greater than 4000 µg/mL). No evidence of impairment of reproductive function was shown in laboratory animal studies.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Mannitol
Hypromellose
Sodium citrate
Citric acid monohydrate
Disodium edetate
Tyloxapol
Sodium hydroxide and/or
Concentrated hydrochloric acid (for pH-adjustment)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 2 years
The contents and bottle should be discarded 4 weeks after opening the container for the first time.

6.4 Special precautions for storage

Do not store above 25°C. Store upright.

6.5 Nature and contents of container

Natural low-density polyethylene bottle with natural low-density polyethylene dispensing plug and tamper evident polypropylene screw cap, containing 5 ml or 10 ml of solution.

Not all pack sizes may be marketed.

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

Novartis Ireland Limited
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Elm Park
Merrion Road
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8 MARKETING AUTHORISATION NUMBER

PA0896/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 December 1991

Date of last renewal: 16 December 2006

10 DATE OF REVISION OF THE TEXT

July 2018