Allergan Expands Dry Eye Portfolio With Launch of REFRESH OPTIVE™ Advanced Lubricant Eye Drops

REFRESH OPTIVE™ Advanced is an over-the-counter artificial tear option for patients suffering from Dry Eye symptoms. As the latest innovation to the broad Allergan Dry Eye management portfolio, REFRESH OPTIVE™ Advanced is a lipid-enhanced tear with the low blur and the comfort of an aqueous tear. Its comprehensive, triple-action formulation works on all 3 layers of the tear film:
- Stabilize lipid layer/reduce tear evaporation
- Hydrate aqueous layer
- Lubricate and protect mucin layer

REFRESH OPTIVE™ Advanced also penetrates the surface to provide osmoprotection to the corneal epithelial cells from excessive salt levels. It does not separate, resulting in no shaking required prior to use. REFRESH OPTIVE™ Advanced is an innovative artificial tear that overcomes the challenges of delivering lipid to the tear film. Specifically, the tear is stable in the bottle but rapidly and efficiently releases lipid when mixed with salts found in human tears,” said Joseph Vehige, OD, Allergan Senior Director, Consumer Eye Care Research and Development. “The resulting benefits are low viscosity and low lipid content overall, giving improved product clarity and comfort.”

Whether your patients use an artificial tear with Dry Eye prescription therapies or without, recommend REFRESH OPTIVE™ Advanced, a triple-MOA formula for Dry Eye symptom relief.

The Allergan line of REFRESH OPTIVE™ brand products can be found at retail locations where over-the-counter eye care products are sold.

To find out more about REFRESH OPTIVE™ Advanced, please visit www.refreshbrand.com.

As Allergy Season Approaches, Consider LASTACAFT® (Alcaftadine Ophthalmic Solution) 0.25%

You’ll be seeing more allergy patients in the coming months. Thankfully, LASTACAFT® is here!

Since the launch of LASTACAFT® in 2011, Allergan has been working with managed care organizations to give more patients access to this product. Now, 87% of all Commercial patients are covered for LASTACAFT™—just one of the reasons to take a closer look at this treatment.

INDICATIONS AND USAGE
LASTACAFT® is an H₁ histamine receptor antagonist indicated for the prevention of itching associated with allergic conjunctivitis.

MECHANISM OF ACTION
Alcaftadine is an H₁, histamine receptor antagonist and inhibitor of the release of histamine from mast cells. Decreased chemotaxis and inhibition of eosinophil activation have also been demonstrated.

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS
To minimize contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use.

Patients should be advised not to wear a contact lens if their eye is red.

LASTACAFT® should not be used to treat contact lens-related irritation.

LASTACAFT®:
- Proven to prevent itching due to allergic conjunctivitis all day through 16 hours
- Classified as a Pregnancy Category B product
- Approved for use in patients down to 2 years of age

Remove contact lenses prior to instillation of LASTACAFT®. The preservative in LASTACAFT® benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of LASTACAFT®.

LASTACAFT® is for topical ophthalmic use only.

ADVERSE REACTIONS
The most frequent ocular adverse reactions, occurring in < 4% of LASTACAFT® treated eyes, were eye irritation, burning and/or stinging upon instillation, eye redness, and eye pruritus.

The most frequent non-ocular adverse reactions, occurring in < 3% of subjects with LASTACAFT® treated eyes, were nasopharyngitis, headache, and influenza. Some of these events were similar to the underlying disease being studied.

Please see accompanying full Prescribing Information.

To download a rebate that allows eligible patients to save up to 50% on their LASTACAFT® prescription, visit www.AllerganOptometry.com. Click on the LASTACAFT® logo in the globe to learn more and find the rebate.

Explore the Allergan optometry-dedicated website and register for updates so you’ll always know when new resources are available to you!

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE
LASTACAFT® is an H, histamine receptor antagonist indicated for the prevention of itching associated with allergic conjunctivitis.

2 DOSAGE AND ADMINISTRATION
Instill one drop in each eye once daily.

3 DOSAGE FORMS AND STRENGTHS
Topical ophthalmic solution containing alcaftadine, 0.25% (2.5 mg/mL).

4 CONTRAINDICATIONS
None.

5 WARNINGS AND PRECAUTIONS

5.1 Contamination of Tip and Solution
To minimize contaminating the dropper tip and solution, care should be taken not to touch the eyelid or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use.

5.2 Contact Lens Use
Patients should be advised not to wear a contact lens if their eye is red. LASTACAFT® should not be used to treat contact lens-related irritation.

LASTACAFT® should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of LASTACAFT®. The preservative in LASTACAFT®, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of LASTACAFT®.

5.3 Topical Ophthalmic Use Only
LASTACAFT® is for topical ophthalmic use only.

6 ADVERSE REACTIONS
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

6.1 Ocular Adverse Reactions
The most frequent ocular adverse reactions, occurring in < 4% of LASTACAFT® treated eyes, were eye irritation, burning and/or stinging upon instillation, eye redness and eye pruritus.

6.2 Non-ocular Adverse Reactions
The most frequent non-ocular adverse reactions, occurring in < 3% of subjects with LASTACAFT® treated eyes, were nasopharyngitis, headache and influenza. Some of these events were similar to the underlying disease being studied.

7 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Pregnancy Category B. Reproduction studies performed in rats and rabbits revealed no evidence of impaired female reproduction or harm to the fetus due to alcaftadine. Oral doses in rats and rabbits of 20 and 80 mg/kg/day, respectively, produced plasma exposure levels approximately 200 and 9000 times the plasma exposure at the recommended human ocular dose. There are however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

8.3 Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when LASTACAFT® is administered to a nursing woman.

8.4 Pediatric Use
Safety and effectiveness in pediatric patients below the age of 2 years have not been established.

8.5 Geriatric Use
No overall differences in safety or effectiveness were observed between elderly and younger subjects.

11 DESCRIPTION
LASTACAFT® is a sterile, topically administered H, receptor antagonist containing alcaftadine for opthalmic use. Alcaftadine is a white to yellow powder with an empirical formula of C$_{19}$H$_{24}$N$_{2}$O and a molecular weight of 307.39.

Contains: Active: alcaftadine 0.25% (2.5 mg/mL). Preservative: benzalkonium chloride 0.005%. Inactives: edetate disodium; sodium phosphate, monobasic; purified water; sodium chloride; sodium hydroxide; and/or hydrochloric acid to adjust pH. Chemical Name: 6,11-dihydro-11-(1-methyl-4-piperidinylidine)-5H-imidazo[2,1-b][3] benzazepine-3-carboxaldehyde

Structural Formula:
The drug product has a pH of approximately 7 and an osmolality of approximately 290 mOsm/kg.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
Alcaftadine is an H, histamine receptor antagonist and inhibitor of the release of histamine from mast cells. Decreased chemotaxis and inhibition of eosinophil activation has also been demonstrated.

12.3 Pharmacokinetics
Absorption
Following bilateral topical ocular administration of alcaftadine opthalmic solution, 0.25%, the mean plasma C$_{max}$ of alcaftadine was approximately 60 pg/mL and the median T$_{max}$ occurred at 15 minutes. Plasma concentrations of alcaftadine were below the lower limit of quantification (10 pg/mL) by 3 hours after dosing. The mean C$_{max}$ of the active carboxylic acid metabolite was approximately 3 ng/mL and occurred at 1 hour after dosing. Plasma concentrations of the carboxylic acid metabolite were below the lower limit of quantification (100 pg/mL) by 12 hours after dosing. There was no indication of systemic accumulation or changes in plasma exposure of alcaftadine or the active metabolite following daily topical ocular administration.

Distribution
The protein binding of alcaftadine and the active metabolite are 39.2% and 62.7%, respectively.

Metabolism
The metabolism of alcaftadine is mediated by non-CYP450 cytosolic enzymes to the active carboxylic acid metabolite.

Excretion
The elimination half-life of the carboxylic acid metabolite is approximately 2 hours following topical ocular administration. Based on data following oral administration of alcaftadine, the carboxylic acid metabolite is primarily eliminated unchanged in the urine.

In vitro studies showed that neither alcaftadine nor the carboxylic acid metabolite substantially inhibited reactions catalyzed by major CYP450 enzymes.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Alcaftadine was not mutagenic or genotoxic in the Ames test, the mouse lymphoma assay or the mouse micronucleus assay.

Alcaftadine was found to have no effect on fertility of male and female rats at oral doses up to 20 mg/kg/day (approximately 200 times the plasma exposure at the recommended human ocular dose).

14 CLINICAL STUDIES
Clinical efficacy was evaluated in conjunctival allergen challenge (CAC) studies. LASTACAFT® was more effective than its vehicle in preventing ocular itching in patients with allergic conjunctivitis induced by an ocular allergen challenge, both at 3 minutes post-dosing and at 16 hours post-dosing of LASTACAFT®. The safety of LASTACAFT® was evaluated in a randomized clinical study of 909 subjects over a period of 6 weeks.

16 HOW SUPPLIED/STORAGE AND HANDLING
LASTACAFT® (alcaftadine ophthalmic solution) 0.25% is supplied in an opaque, white low-density polyethylene bottle with a white propylene cap. 3 mL fill in 5 mL bottle NDC 0023-4290-03


17 PATIENT COUNSELING INFORMATION

17.1 Sterility of Dropper Tip
Patients should be advised to not touch dropper tip to any surface, as this may contaminate the contents.

17.2 Concomitant Use of Contact Lenses
Patients should be advised not to wear a contact lens if their eye is red. Patients should be advised that LASTACAFT® should not be used to treat contact lens-related irritation. Patients should also be advised to remove contact lenses prior to instillation of LASTACAFT®. The preservative in LASTACAFT®, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of LASTACAFT®.

17.3 Topical Ophthalmic Use only
For topical ophthalmic administration only.


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