Meeting With Your Eye Doctor: Discussion Guide

Take this brief guide with you to your next office visit to discuss your itchy eyes due to eye allergies.

Seasonal allergies: Do your eyes itch during spring, summer, or fall because of eye allergies caused by allergens like ragweed?

Year-round allergies: Do your eyes itch all year long because of eye allergies caused by allergens like cat dander?

Pregnancy: Are you pregnant or think you may become pregnant? Please inform your eye doctor and ask for appropriate treatment recommendations.

Children: Do you have any kids at least 2 years old who have itchy eyes due to eye allergies? Ask your eye doctor if LASTACAFT® is an appropriate treatment for your child.

Prescription for prevention: Talk to your eye doctor about the benefits and risks of a prescription medicine approved for the prevention of itching associated with eye allergies.

Savings programs available: Find out how you can save on your LASTACAFT® prescription.

APPROVED USE
LASTACAFT® (alcaftadine ophthalmic solution) 0.25% is a prescription medicine approved for the prevention of itching associated with eye allergies.

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS
To minimize contaminating the dropper tip of the bottle and solution, do not touch your eyelids or the areas around your eyes with the dropper tip. Keep bottle tightly closed when not in use.
Do not wear a contact lens if your eye is red.
LASTACAFT® should not be used to treat contact lens-related irritation.
Remove contact lenses before putting LASTACAFT® in your eyes. The preservative in LASTACAFT® may be absorbed by soft contact lenses. Lenses may be put back in your eyes 10 minutes after using LASTACAFT®
LASTACAFT® is for topical use in your eyes only.

SIDE EFFECTS
The most common eye-related side effects that were reported in less than 4% of LASTACAFT® treated eyes were: eye irritation, burning and/or stinging in the eyes after use, eye redness, and eye itching.
The most common non–eye-related side effects that were reported in less than 3% of patients with LASTACAFT® treated eyes were: inflammation of the nose and the upper part of the throat, headache, and the flu. Some of these side effects were similar to the symptoms of eye allergies.

Please see accompanying full Prescribing Information.
HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use LASTACAFT® safely and effectively. See full prescribing information for LASTACAFT®:

LASTACAFT® (alcaftadine ophthalmic solution) 0.25%
Initial U.S. Approval: 2010

INDICATIONS AND USAGE

LASTACAFT® is an H1 histamine receptor antagonist indicated for the prevention of itching associated with allergic conjunctivitis. (1)

DOSAGE AND ADMINISTRATION

Instill one drop in each eye once daily. (2)

DOSAGE FORMS AND STRENGTHS

Ophthalmic solution containing alcaftadine, 0.25% (2.5 mg/mL) (3)

WARNINGS AND PRECAUTIONS

• To minimize the risk of contamination, do not touch dropper tip to any surface. Keep bottle tightly closed when not in use. (5.1)
• LASTACAFT® should not be used to treat contact lens-related irritation. (5.2)
• Remove contact lenses prior to instillation of LASTACAFT® (5.2)

ADVERSE REACTIONS

The most common ocular adverse reactions, occurring in < 4% of LASTACAFT® treated eyes, were eye irritation, burning and/or stinging on instillation, eye redness, and eye pruritus. (6.1)

The most common non-ocular adverse reactions, occurring in < 3% of subjects with LASTACAFT® treated eyes, were nasopharyngitis, headache and influenza. (6.2)

To report SUSPECTED ADVERSE REACTIONS, contact Allergan at 1-800-433-8871 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION

Revised: 09/2011

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
  5.1 Contamination of Tip and Solution
  5.2 Contact Lens Use
  5.3 Topical Ophthalmic Use Only
6 ADVERSE REACTIONS
  6.1 Ocular Adverse Reactions
  6.2 Non-ocular Adverse Reactions
8 USE IN SPECIFIC POPULATIONS
  8.1 Pregnancy
  8.3 Nursing Mothers
  8.4 Pediatric Use
  8.5 Geriatric Use
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
  12.1 Mechanism of Action
  12.3 Pharmacokinetics
13 NONCLINICAL TOXICOLOGY
  13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
14 CLINICAL STUDIES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION
  17.1 Sterility of Dropper Tip
  17.2 Concomitant Use of Contact Lenses
  17.3 Topical Ophthalmic Use Only

*Sections or subsections omitted from the full prescribing information are not listed
1 INDICATIONS AND USAGE
LASTACAFT® is an H₁ 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 eyelids 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.

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.

8 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, administered to a nursing woman.

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.

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 polypropylene 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.

17.3 Topical Ophthalmic Use only
For topical ophthalmic administration only.

FULL PRESCRIBING INFORMATION

12 CLINICAL PHARMACOLOGY

12.1 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 has also been demonstrated.

12.3 Pharmacokinetics
Absorption
Following bilateral topical ocular administration of alcaftadine ophthalmic solution, 0.25%, the mean plasma Cₘₐₓ of alcaftadine was approximately 60 pg/mL and the median Tₘₐₓ 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 Cₘₐₓ 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.

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®.

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.

Manufactured for Allergan, Inc., Irvine, CA 92612, U.S.A.
©2011 Allergan, Inc. * marks owned by Allergan, Inc.
Made in the U.S.A.
Based on 72409US11C
APC14E111