DO YOU HAVE ITCHY ALLERGY EYES?

ITCH ITCH ITCH

RUB RUB RUB

Find out about lasting relief
Common causes of itching due to eye allergies include:

- Pollen from trees, grasses, and ragweed
- Dust mites
- Cat dander

Approximately 10 million people are allergic to cat dander, the most common pet allergy.
How common is it?

About 20% of people have eye allergies. For those who do, itchy eyes is a very common symptom.

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.

Please see more Important Safety Information on the following pages.
UNDERSTANDING ALLERGENS THAT CAUSE ITCHY EYES

What are allergens?

Allergens are what trigger your eye allergies. To the body, allergens are considered foreign substances that threaten or irritate the body, such as pollen from ragweed or cat dander. If you react to certain allergens, this means your eyes have become sensitized at some point. Therefore, when your eyes come into contact with specific allergens, an allergic response results.

Eye allergies are grouped in various ways, one of which is where the allergens are located—indoors or outdoors. Some allergens are more likely to be found indoors. Others you’re more likely to be exposed to outdoors.

INDOOR ALLERGENS
Examples of common indoor allergens that may cause itchy eyes are airborne cat dander and dust mites.

OUTDOOR ALLERGENS
Examples of common outdoor allergens that often trigger itchy eyes are grass, tree, and ragweed pollens.
WARNINGS AND PRECAUTIONS (continued)

Do not wear a contact lens if your eye is red.

LASTACAFT® (alcaftadine ophthalmic solution) 0.25% should not be used to treat contact lens-related irritation.

Please see more Important Safety Information on the following pages.

POLLEN MAP

Common pollens in your area

Pollens affect people at different times during the year. Visit Lastacaft.com to explore the interactive US Pollen Map. You will find out when common pollens are most likely to thrive in your area.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Do not wear a contact lens if your eye is red.

LASTACAFT® (alcaftadine ophthalmic solution) 0.25% should not be used to treat contact lens-related irritation.

Please see more Important Safety Information on the following pages.
ALLERGEN MANAGEMENT TIPS

In the home

When the outdoor air is filled with pollen, people with eye allergies often try to control their symptoms by staying indoors. But for people who are sensitive to indoor allergens, there are things you can do in the home that may help.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)
Remove contact lenses before putting LASTACAFT® (alcaftadine ophthalmic solution) 0.25% 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.
Please see more Important Safety Information on the following pages.
Tips to reduce indoor allergens

Clean your house
• Get rid of the allergen sources. Wearing a dust mask while cleaning can help reduce exposure to allergens

Rid your bedroom of allergen sources
• Pay special attention to cleaning the bedroom you sleep in

Vacuum at least once a week
• Use a vacuum with a HEPA filter or special double filter bags to avoid releasing allergens into the air. Use a damp or treated cloth for dusting and leave the house for several hours after cleaning it

Keep windows and doors closed
• Prevent pollen entry

Avoid cat dander
• If you are allergic to cat dander, it is suggested not to keep pets in the house, and if you do, to keep pets out of the bedroom

Eliminate dust mites
• Make sure surfaces in the home stay clean and tidy. Uncarpeted, hard floors are best throughout the home and especially in the bedroom. Put allergen-impermeable covers on all pillows and mattresses, which is even more effective than using air cleaners. Wash bedding weekly in hot water (130°F) to kill dust mites
How to treat itchy allergy eyes

When your eyes itch because of eye allergies, one thing that matters is getting lasting relief.

You can get that with LASTACAFT® (alcaftadine ophthalmic solution) 0.25%—a prescription eyedrop that works at 3 minutes and lasts all day; just one drop, once a day, helps you prevent itchy allergy eyes through a full 16 hours.
IMPORTANT SAFETY INFORMATION (continued)
SIDE EFFECTS
The most common eye-related side effects that were reported in less than 4% of LASTACAFT® (alcaftadine ophthalmic solution) 0.25% treated eyes were: eye irritation, burning and/or stinging in the eyes after use, eye redness, and eye itching.

Please see more Important Safety Information on the following pages.

HOW LASTACAFT® WORKS

Itch prevention:
• LASTACAFT® (alcaftadine ophthalmic solution) 0.25% interferes with a specific type of chemical process that causes itchy eyes in people with allergies

Histamine blocking:
• LASTACAFT® (alcaftadine ophthalmic solution) 0.25% blocks the release of histamine from certain cells
CLINICAL STUDY RESULTS

Effectiveness

- LASTACAFT® (alcaftadine ophthalmic solution) 0.25% effectively prevents itching due to eye allergies
- LASTACAFT® (alcaftadine ophthalmic solution) 0.25% works fast (at 3 minutes) and prevents itchy eyes all day (through 16 hours)

Side Effects

LASTACAFT® ophthalmic solution was also evaluated for safety in a separate clinical study of 909 patients over 6 weeks.

The most common eye-related side effects were reported in less than 4% of patients treated with LASTACAFT® and included:
- Eye irritation
- Burning and/or stinging in the eyes after use
- Eye redness
- Eye itching

The most common non-eye-related side effects were reported in less than 3% of patients treated with LASTACAFT® ophthalmic solution and included:
- Inflammation of the nose and the upper part of the throat
- Headache
- The flu
IMPORTANT SAFETY INFORMATION (continued)
SIDE EFFECTS (continued)
The most common non–eye-related side effects that were reported in less than 3% of patients with LASTACAFT® (alcaftadine ophthalmic solution) 0.25% 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.
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.

Please see inside for more Important Safety Information.
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*

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*Sections or subsections omitted from the full prescribing information are not listed.
**FULL PRESCRIBING INFORMATION**

11 DESCRIPTION LASTACAFT® is a sterile, topically administered H, receptor antagonist containing alcaftadine for ophthalmic use.

Alcaftadine is a white to yellow powder with an empirical formula of C_{19}H_{21}N_{3}O and a molecular weight of 307.39.

**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 ophthalmic 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 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. 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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Based on 72409US11C

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