

# BEPREVE<sup>®</sup>

(bepotastine besilate  
ophthalmic solution) 1.5%

ORDER TODAY

**New 5mL Size !**

## Allergy Season is here!

Physicians have requested a smaller size of BEPREVE for patients with short-term ocular itching associated with allergic conjunctivitis and ISTA Pharmaceuticals has responded. Doctors will be prescribing the new size of BEPREVE. Be prepared for the demand!  
Order BEPREVE today!

- BEPREVE has been well received by physicians, patients, and managed care plans
- BEPREVE competes in a \$600 million ophthalmic allergy market
- BEPREVE is the fastest growing product in its category in 2010\*
- ISTA has expanded its professional sales force by 60% to effectively promote BEPREVE to ophthalmologists, optometrists, and allergists.



**Fastest growing product in 2010\***

**\$600 million market**

**ORDER TODAY**

Stocking Information					
Proprietary Name	Active Ingredient	Dosage Form	Strength	Package	NDC
BEPREVE	Bepotastine besilate	Solution drops; ophthalmic	1.5%	10mL	67425-007-75
BEPREVE	Bepotastine besilate	Solution drops; ophthalmic	1.5%	5mL	67425-007-50

The most common adverse reaction occurring in approximately 25% of patients was a mild taste following instillation. Other adverse reactions occurring in 2%-5% of patients were eye irritation, headache, and nasopharyngitis. BEPREVE should not be used to treat contact lens-related irritation.

\*Fastest growing product in its category in the U.S.

Introducing BEPREVE  
–Quick, Comfortable,  
Long-lasting ocular itch relief



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See reverse for brief prescribing information. To learn more about BEPREVE, talk to your ISTA Sales Representative

# **BEPREVE**<sup>®</sup> (bepotastine besilate ophthalmic solution) 1.5%

## BRIEF SUMMARY

### INDICATIONS AND USAGE

BEPREVE (bepotastine besilate ophthalmic solution) 1.5% is a histamine H<sub>1</sub> receptor antagonist indicated for the treatment of itching associated with signs and symptoms of allergic conjunctivitis.

### DOSAGE AND ADMINISTRATION

Instill one drop of BEPREVE into the affected eye(s) twice a day (BID).

### CONTRAINDICATIONS

None.

### WARNINGS AND PRECAUTIONS

#### 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.

#### Contact Lens Use

Patients should be advised not to wear a contact lens if their eye is red. BEPREVE should not be used to treat contact lens-related irritation. BEPREVE should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of BEPREVE. The preservative in BEPREVE, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of BEPREVE.

#### Topical Ophthalmic Use Only

BEPREVE is for topical ophthalmic use only.

### ADVERSE REACTIONS

The most common reported adverse reaction occurring in approximately 25% of subjects was a mild taste following instillation. Other adverse reactions occurring in 2-5% of subjects were eye irritation, headache, and nasopharyngitis.

### USE IN SPECIFIC POPULATIONS

#### Pregnancy

**Pregnancy Category C:** Teratogenicity studies have been performed in animals. Bepotastine besilate was not found to be teratogenic in rats during organogenesis and fetal development at oral doses up to 200 mg/kg/day (representing a systemic concentration approximately 3,300 times that anticipated for topical ocular use in humans), but did show some potential for causing skeletal abnormalities at 1,000 mg/kg/day. There were no teratogenic effects seen in rabbits at oral doses up to 500 mg/kg/day given during organogenesis and fetal development (>13,000 times the dose in humans on a mg/kg basis).

There are no adequate and well-controlled studies of bepotastine besilate in pregnant women. Because animal reproduction studies are not always predictive of human response, BEPREVE (bepotastine besilate ophthalmic solution) 1.5% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

#### Nursing Mothers

It is not known if bepotastine besilate is excreted in human milk. Caution should be exercised when BEPREVE (bepotastine

besilate ophthalmic solution) 1.5% is administered to a nursing woman.

#### Pediatric Use

Safety and efficacy of BEPREVE (bepotastine besilate ophthalmic solution) 1.5% have not been established in pediatric patients under 2 years of age. Efficacy in pediatric patients under 10 years of age was extrapolated from clinical trials conducted in pediatric patients greater than 10 years of age and from adults.

#### Geriatric Use

No overall difference in safety or effectiveness have been observed between elderly and younger patients.

### PATIENT COUNSELING INFORMATION

#### Topical Ophthalmic Use Only

For topical ophthalmic administration only.

#### Sterility of Dropper Tip

Patients should be advised to not touch dropper tip to any surface, as this may contaminate the contents.

#### 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 BEPREVE should not be used to treat contact lens-related irritation.

#### Rx only

Manufactured for: ISTA Pharmaceuticals<sup>®</sup>, Inc.  
Irvine, CA 92618

By: Bausch & Lomb Incorporated  
Tampa, FL 33637

Under license from:  
Senju Pharmaceutical Co., Ltd.  
Osaka, Japan 541-004

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U.S. Patents: 6,307,052; 6,780,877  
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BRV848-5/10

