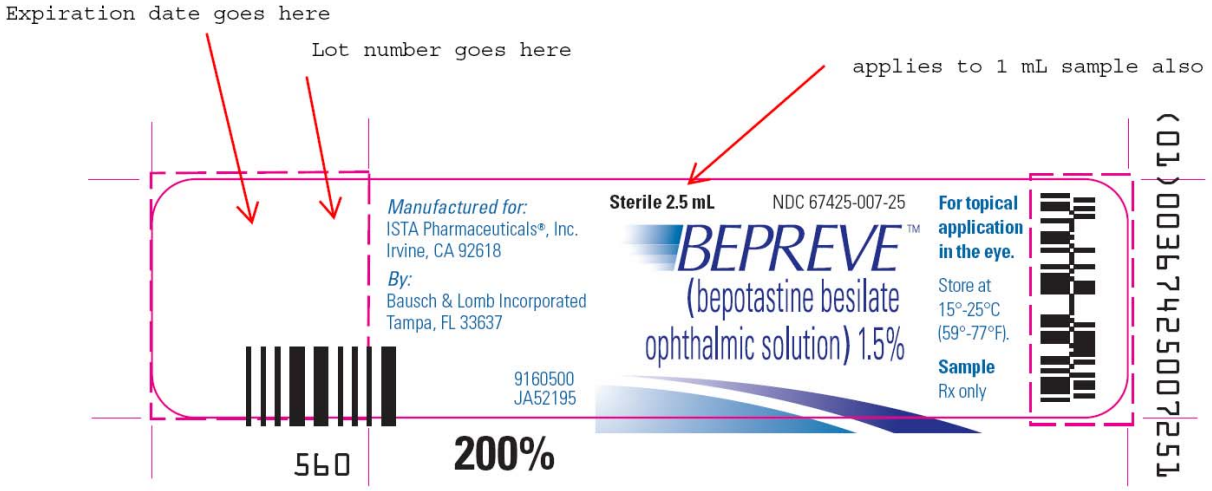
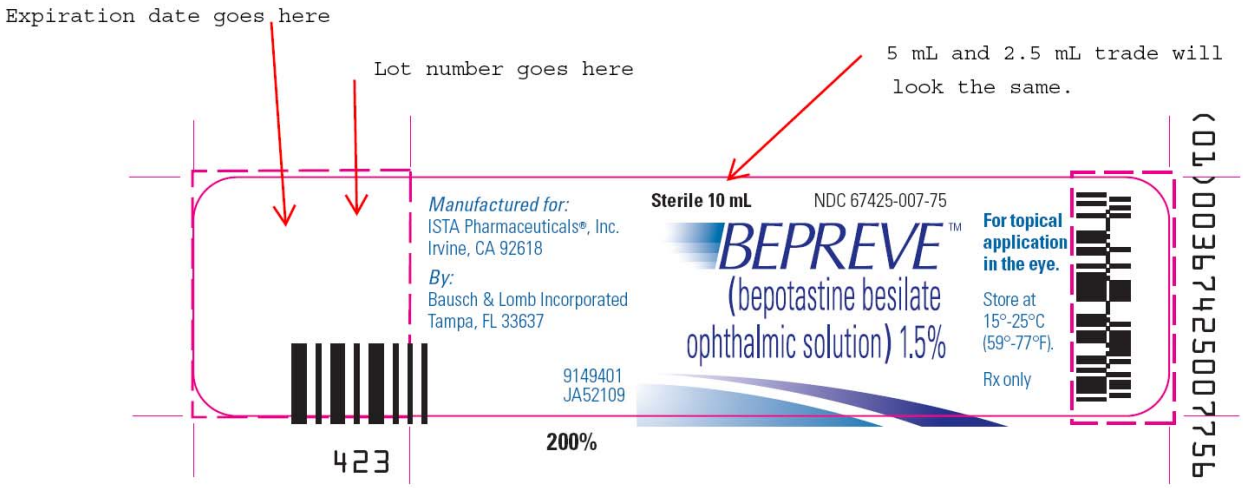
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
22-288

LABELING

Container Labels (1 mL, and 2.5 mL samples, 2.5 ml and 5 mL trade)





Carton Labels (1 mL, and 2.5 mL samples, 2.5 ml and 5 mL trade)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Bepreve™ (bepotastine besilate ophthalmic solution) 1.5% safely and effectively.
See full prescribing information for Bepreve™.

BEPREVE™
(bepotastine besilate ophthalmic solution) 1.5%
Initial U.S. Approval: 2009

----------INDICATIONS AND USAGE---------

Bepreve™ is a histamine H_1 receptor antagonist indicated for the treatment of itching associated with allergic conjunctivitis. (1)

--------DOSAGE AND ADMINISTRATION----

Instill one drop into the affected eye(s) twice a day. (BID). (2)

-------DOSAGE FORMS AND STRENGTHS--

Solution containing bepotastine besilate, 1.5%. (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)
- **Bepreve™** should not be used to treat contact lens-related irritation. (5.2)
- Remove contact lenses prior to instillation of **Bepreve™.** (5.2)

----------ADVERSE REACTIONS----------

The most common adverse reaction occurring in approximately 25% of patients was a mild taste following instillation. Other adverse reactions which occurred in 2-5% of subjects were eye irritation, headache, and nasopharyngitis. (6)

To report SUSPECTED ADVERSE REACTIONS, contact ISTA Pharmaceuticals, Inc. at 1-877-788-2020, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION

Revised: 08/2009

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

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