

FIRST TIME GENERIC APPROVAL

Brand Name	Bepreve®
Generic Name	bepotastine besilate
Drug Manufacturer	Mylan Pharmaceuticals Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First time generics

FDA APPROVAL DATE

March 18, 2019

LAUNCH DATE

Jun 2, 2021

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 206220

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Bepotastine besilate ophthalmic solution is a histamine h1 receptor antagonist indicated for the treatment of itching associated with allergic conjunctivitis.

MECHANISMS OF ACTION

Bepotastine is a topically active, direct H1-receptor antagonist and an inhibitor of the release of histamine from mast cells.

DOSE FORM AND STRENGTH

Ophthalmic solution containing bepotastine besilate, 15 mg/ml (1.5%).

DOSE & ADMINISTRATION

- Instill one drop into the affected eye(s) twice a day.
- Remove contact lenses prior to instillation of bepotastine besilate ophthalmic solution.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.