

CLINICAL UPDATE

Brand Name	Cystadrops®
Generic Name	Cysteamine ophthalmic solution
Drug Manufacturer	Recordati Rare Diseases

Clinical Update

Clinical Update: U.S. FDA Approves Cystadrops® (Cysteamine Ophthalmic Solution) 0.37%, A New Practical Treatment Option for the Ocular Manifestations of Cystinosis

FDA Approval Date: August 19, 2020

Launch Date: Not available

Overview

Cystadrops® is an ophthalmic anticystine agent. The medication converts cystine to cysteine and cysteine-cysteamine mixed disulfides and reduces corneal cystine crystal accumulation. It is indicated for the treatment of corneal cystine crystal deposits in adults and children with ocular cystinosis.

It is the only FDA-approved cysteamine drop formulation with four times a day dosing. Cystinosis is a rare genetic condition present from birth that leads to the build-up of cystine crystals throughout the body, causing widespread tissue and organ damage and significant impact on the eyes.

Efficacy

The FDA approval of Cystadrops® was supported by data from two clinical trials, both in which patients received Cystadrops® at a median frequency of four times per day. A Phase 3 open-label, randomized, controlled, two-arm multicenter trial, with 15 patients in the Cystadrops® arm, investigated the reduction in corneal cystine crystal density as assessed by in vivo confocal microscopy (IVCM). In the Cystadrops® arm, the trial showed a 40 percent reduction in the IVCM total score across all corneal layers from baseline to 90 days.

Dose & Administration

Instill one drop of Cystadrops® in each eye, 4 times a day during waking hours.

Dosage Form & Strength: Topical ophthalmic solution containing 3.8 mg/mL (0.37%) of cysteamine.

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.