

September 1, 2020

Dear Cystinosis Community:

Leadiant Biosciences, Inc. recently informed the FDA that we would not be able to meet the expected short-term demand for Cystaran® (cysteamine ophthalmic solution) 0.44% eye drops. Today, Leadiant was able to obtain one batch of Cystaran from the manufacturer. We remain committed to every cystinosis patient and are working to rapidly restore the supply of treatment in order to minimize any impact on patients.

Cystaran is made for Leadiant by Hi-Tech Pharmacal Co., a subsidiary of Akorn, Inc., a contract manufacturing facility that is independently owned and operated. Leadiant has had recent difficulty procuring batches from Hi-Tech, which is currently subject to corporate reorganization under impending bankruptcy proceedings.

We are working diligently to have the batch finalized and available at the specialty pharmacy for distribution as soon as possible. There is still a brief period for which the product may not be available. We are intent on identifying an alternative manufacturer to avoid situations like this moving forward.

Notification of the shortage has been communicated to the pharmacy where you normally fill your prescription, doctors who prescribe Cystaran, and the FDA. We will communicate with the pharmacy all updates and product availability.

Patients should speak with their healthcare provider about how this may impact their treatment plan.

Please know that everyone at Leadiant is determined to find a resolution as quickly as possible. We have been committed to the cystinosis community for more than 20 years, and care deeply about every patient. We know you count on Cystaran and Leadiant, and we are dedicated to working with you through this time. If you have any questions, please do not hesitate to reach out to Lesli King [Lesli.King@Leadiant.com](mailto:Lesli.King@Leadiant.com) or call at 301-670-5450.

Thank you,  
Your Leadiant Team

**Indication:**

CYSTARAN (CYSTEAMINE OPHTHALMIC SOLUTION) 0.44% STERILE is a cystine-depleting agent indicated for the treatment of corneal cystine crystal accumulation in patients with cystinosis.

By prescription only.

**Important Safety Information:**

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. There have been reports of benign intracranial hypertension (or pseudotumor cerebri) associated with oral cysteamine treatment that has resolved with the addition of diuretic therapy. There have also been reports associated with ophthalmic use of cysteamine; however, all of these patients were on concurrent oral cysteamine.

CYSTARAN contains benzalkonium chloride, which may be absorbed by soft contact lenses. Contact lenses should be removed prior to application of solution and may be reinserted 15 minutes following its administration.

CYSTARAN is for topical ophthalmic use only.

The most frequently reported ocular adverse reactions occurring in  $\geq 10\%$  of patients were sensitivity to light, redness, and eye pain/irritation, headache and visual field defects.