

February 12, 2021

Dear Cystinosis Community:

We wanted to share an update from Leadiant Biosciences regarding the CYSTARAN® (cysteamine ophthalmic solution) 0.44%® eye drops shortage. As you all know, we announced in October 2020 that CYSTARAN went into shortage. The reason why CYSTARAN went into shortage is because Leadiant was working with an independent manufacturer to make CYSTARAN, and that manufacturer is restructuring its business under Chapter 11 of the Bankruptcy Code. The restructuring of this manufacturer during this bankruptcy and various associated issues have affected the continuous production of CYSTARAN.

Fortunately, we have chosen a new manufacturer to begin producing CYSTARAN with a proven track record and expertise in manufacturing. This new partner implemented a new technology that will enable a more consistent and reliable manufacturing process, following the U.S. Food and Drug Administration's (FDA) standards and requirements.

We are confident that these improvements will greatly reduce the risk of recalls and shortages with the newly manufactured supply of CYSTARAN moving forward.

There will not be any changes to the formulation of the eye drops themselves. You will receive the same eye drops that you are used to. Unfortunately, we are not yet able to provide an estimate of timing for the release of CYSTARAN from our new manufacturer. We can say that our activities with our new manufacturer, which have to be approved by the FDA, are advanced and we're working very hard to restore supply as soon as possible.

We have been committed to the cystinosis community for more than 20 years and we know how much trust you put in us. We will continue to provide updates regarding when the supply of CYSTARAN will be fully restored.

If you have any questions about the shortage, do not hesitate to reach out to me. If you have any questions regarding your treatment plan, you should discuss with your physician.

Thank you,
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