

# New Clinical Study Shows Promise for Dietary Management of Hyperoxaluria

*Innovative enzyme was effective in 94% of study subjects*

GAINESVILLE, FL, UNITED STATES, May 8, 2019 /EINPresswire.com/ -- A new enzyme-based product may provide much-needed support for managing hyperoxaluria through a low-oxalate diet as part of the dietary management of calcium-oxalate kidney stones, according to clinical trial results presented at the American Urology Association (AUA)'s 2019 National Meeting last week.

Ox-1, Captozyme's proprietary oxalate decarboxylase enzyme — marketed as [Nephure™](#) and distributed through their subsidiary, Entring LLC — significantly decreased urinary oxalate in 94% of participants, as demonstrated by the prospective, double-blind, randomized, placebo-controlled, cross-over study of 33 healthy volunteers. Within-subject mean difference in 24-hour urinary oxalate was 12.6 mg or 30% ( $p < 0.0001$ ) when comparing treatment vs. baseline on a high-oxalate diet.

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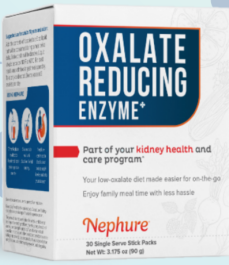
Compliance with physician's recommendations is imperative, but following dietary recommendations can be challenging. [A] product that can help with compliance will offer value to everyone involved.”

*Helena Cowley, CEO,  
Captozyme Inc.*

“Compliance with physician's recommendations is imperative, but following dietary recommendations can be challenging for many individuals. A product that can help with compliance will offer value to everyone involved. We are delighted to share these results with the medical community, confirming the efficacy and potency of our oxalate-reducing enzyme to reduce urinary oxalate,” Helena Cowley, Chief Executive Officer of [Captozyme Inc.](#), said.

The clinical study, sponsored by Captozyme Inc., began in August 2018. Following screening and baseline evaluations,

all study subjects were placed on a two-day high-oxalate diet lead-in that resulted in an elevation of urinary oxalate to approximately 43mg/24 hours. Subjects were then randomized to one of two cross-over treatment sequences (Nephure™ to placebo or placebo to Nephure™) while maintaining the controlled high-oxalate, low-calcium meal plan consisting of standard Western meals with added spinach and rhubarb to provide additional levels of oxalate intake. Study subjects ate between 750 to 800 mg of oxalate and 500 to 550 mg of calcium per day and took Nephure™ or placebo three times per day for two days. At the end of the first treatment period, subjects experienced a two-day wash-out, after which they crossed over and were administered the alternate treatment.



**NEW OPTIONS  
FOR INDIVIDUALS WITH  
HYPEROXALURIA**

Positive results from a prospective, double-blind, randomized, placebo-controlled study with Nephure, an orally administered oxalate-reducing enzyme in 33 healthy subjects provided a controlled diet will be presented at the AUA2019.

Results from Captozyme, Inc.'s post-market study of an innovative enzyme to support kidney health have been accepted for poster presentation on May 4 at the American Urological Association (AUA) Annual Meeting in Chicago.

Eight 24-hour urine collections were performed during the entirety of the study. Apart from the reduction of urinary oxalate, researchers found no other significant differences in any of the urinary parameters measured in the study, including calcium, magnesium, citrate, uric acid and creatinine.

"We attribute the high potency and significant reduction — despite a low dose of enzyme — to the high affinity our enzyme has to oxalate, as well as its sustained activity in the low pH of the stomach. We are excited to continue our clinical development program and further evaluate the potential of this enzyme at higher dose levels," Helena Cowley remarked.

The clinical study will be published later this year. For more information about the clinical study or to download a summary, visit [Captozyme.com/ClinicalStudy](https://www.captozyme.com/ClinicalStudy).

#### About Captozyme

Captozyme, Inc. is a biotechnology company developing enzymes and formulations to advance knowledge in the area of gut health and through its products, advance the health and wellness of people. Captozyme, Inc. also houses a cGMP manufacturing facility for production of Phase 1 clinical trial drug substance with a focus on live biologics development. The company is based in Gainesville, Florida. Learn more about Captozyme by visiting [www.captozyme.com](https://www.captozyme.com).

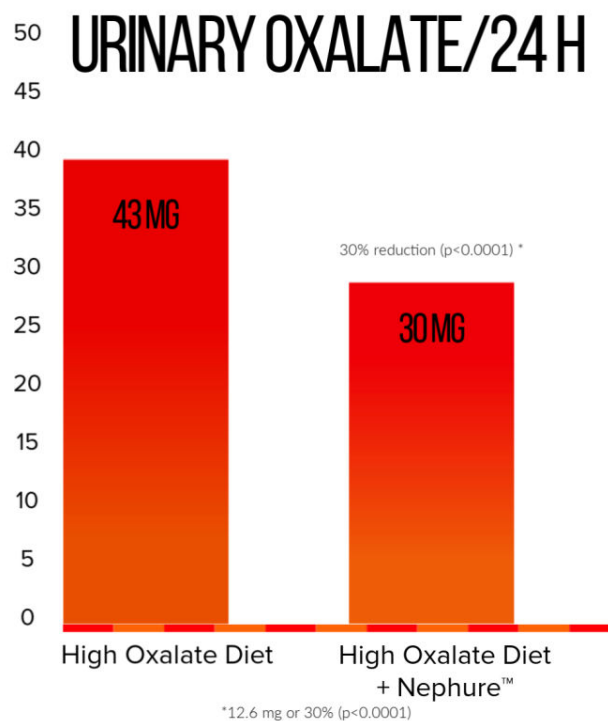
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Helena Cowley, CEO, Captozyme Inc., shares the positive results of the clinical study.



About 94% of study participants experienced significant reduction in urinary oxalate. (30% reduction ( $p < 0.0001$ ))

This press release can be viewed online at: <http://www.einpresswire.com>

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