FIRST TIME GENERIC APPROVAL

Brand Name	Thiola®
Generic Name	tiopronin
Drug Manufacturer	Teva Pharmaceuticals USA, Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

April 26, 2021

LAUNCH DATE

May 17, 2021

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 214326

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Tiopronin is a reducing and complexing thiol indicated, in combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation in adults and pediatric patients 9 years of age and older with severe homozygous cystinuria, who are not responsive to these measures alone.

MECHANISMS OF ACTION

The goal of therapy is to reduce urinary cystine concentration below its solubility limit. Tiopronin is an active reducing agent which undergoes thiol-disulfide exchange with cystine to form a mixed disulfide of tiopronin-cysteine. From this reaction, a water soluble mixed disulfide is formed and the amount of sparingly soluble cystine is reduced.

DOSE FORM AND STRENGTH

Tablets: 100 mg

DOSE & ADMINISTRATION

- The recommended initial dosage in adult patients is 800 mg/day. In clinical studies, the average dosage was about 1,000 mg/day.
- The recommended initial dosage in pediatric patients 9 years of age and older is 15 mg/kg/day. Avoid dosages greater than 50 mg/kg per day in pediatric patients.

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- Administer tiopronin tablets in 3 divided doses at the same times each day at least one hour before or 2 hours after meals.
- Measure urinary cystine 1 month after initiation of tiopronin tablets and every 3 months thereafter.