INDIVIDUALIZE THIOLA EC® (tiopronin) DOSAGES TO HELP PREVENT STONE FORMATION

Thiola EC (tiopronin) Delayed-Release Tablets 100mg|300mg

START 1

Start with the recommended dose of THIOLA EC.[1]*

Pills shown are not actual size.

- **Adults:** May begin at 800 mg/day.
- **Children ≥20 kg:** May begin at 15 mg/kg/day and avoid dosages >50 mg/kg/day.

MONITOR 2

Measure urinary cystine 1 month after starting THIOLA EC, and every 3 months thereafter.[1]

- Conduct a 24-hour urine test to evaluate your patient's cystine levels.

Regularly monitor for early stone detection:

- Sand/gravel in urine[2]
- Imaging showing presence of stones[3]
- Kidney stone-related pain[4]

ADJUST 3

Reduction of urinary cystine is proportional to THIOLA EC dosage.[1]

- THIOLA EC should be dosed to effect to maintain urinary cystine concentration <250 mg/L.

THIOLA EC Tablet†	Potential Urinary Cystine Reduction
300 mg	~75 mg/day
100 mg	~25 mg/day

Please see Dosing Guide on reverse side.

Reminders[1]

- Advise patients to take THIOLA EC in combination with high fluid intake, alkali, and diet modification.
- Determine if your patient will be taking THIOLA EC with or without food. Taking THIOLA EC with food may decrease the levels of tiopronin in the blood by approximately 25%.
- Instruct your patients to take THIOLA EC in 3 divided doses, the same times each day.
- For patients who cannot swallow the tablet whole, THIOLA EC can be crushed and mixed with applesauce.
- Inform patients about the importance of compliance in order to help prevent stone formation.

*Patients with a history of severe toxicity to d-penicillamine may start at a lower dose.
†The decrement in urinary cystine produced by tiopronin is generally proportional to the dose. A reduction in urinary cystine of 250–350 mg/day at tiopronin dosage of 1 g/day, and a decline of approximately 500 mg/day at a dosage of 2 g/day, may be expected.

Indications and usage

THIOLA EC® (tiopronin, delayed-release tablets) is indicated, in combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation in adults and pediatric patients ≥20 kg with severe homozygous cystinuria, who are not responsive to these measures alone.

Important Safety Information

Contraindications

THIOLA EC is contraindicated in patients with hypersensitivity to tiopronin or any other components of THIOLA EC.

Warnings and precautions

- **Proteinuria:** Proteinuria, including nephrotic syndrome, and membranous nephropathy, has been reported with tiopronin use. Pediatric patients receiving >50 mg/kg of tiopronin per day may be at increased risk for proteinuria. Monitor patients for the development of proteinuria and discontinue therapy in patients who develop proteinuria.
- **Hypersensitivity Reactions:** Hypersensitivity reactions (drug fever, rash, fever, arthralgia and lymphadenopathy) have been reported.

Adverse reactions

The most common adverse reactions (≥10%) are nausea, diarrhea or soft stools, oral ulcers, rash, fatigue, fever, arthralgia, proteinuria, and emesis.

Please see additional Important Safety Information on page 2 and accompanying full Prescribing Information on pages 3 and 4.

THIOLA EC® (tiopronin) DOSING GUIDE

Guidelines to achieve expected cystine concentration based on AUA recommendations[5]

Dosing ranges based on a pH of 7.

24-hr cystine level per day (mg/day)	Urine output per day (L)*	Additional THIOLA EC dose per day (mg)	Expected cystine concentration (mg/L)
500	2	0	250
	2.5	0	200
	3	0	167
	3.5	0	143
	4	0	125
750	2	1000	250
	2.5	500	250
	3	0	250
	3.5	0	214
	4	0	188
1000	2	2000	250
	2.5	1500	250
	3	1000	250
	3.5	500	250
	4	0	250
1250	2	3000	250
	2.5	2500	250
	3	2000	250
	3.5	1500	250
	4	1000	250
1500	2	4000**	250
	2.5	3500**	250
	3	3000	250
	3.5	2500	250
	4	2000	250

*Minimal urine output of 2.5 L/day is recommended.[5]
**Dosages of THIOLA EC above 3000 mg have not been studied.

Goal: Calculate dosing based on patient's cystine levels to achieve cystine concentration at 250 mg/L[1]

Example:

- Cystine level = 725 mg/day
- pH level = 7
- Urine output per day = 2 L/day

The dosing calculation is:

24-hr cystine level/Urine output per day = Expected cystine concentration

THIOLA EC dose: 900 mg/day

Pills shown are not actual size.

Calculate your adult cystinuria patient's dosage at THIOLAECDosingGuide.com

Important Safety Information (cont.)

Drug interactions

Avoid alcohol consumption 2 hours before and 3 hours after taking THIOLA EC as THIOLA EC is released faster in the presence of alcohol.

Specific populations

- **Lactation:** Breastfeeding is not recommended during treatment with THIOLA EC.
- **Geriatric Use:** Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Please see additional Important Safety Information and accompanying full Prescribing Information.

References: 1. THIOLA EC [package insert]. San Antonio, TX: Mission Pharmacal Company. **2.** Biyani et al. *EAU-EBU Update Series*. 2006;4(5):175-183. **3.** Claes et al. *Pediatr Nephrol*. 2012;27(11):2031-2038. **4.** What are cystine stones? The National Kidney Foundation website. https://www.kidney.org/kidney-topics/cystine-kidney-stones. Accessed December 10, 2025. **5.** Pearle et al. *J Urol*. 2014;192(2):316-324.

ThiolaEC (tiopronin) Delayed-Release Tablets 100mg|300mg

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use THIOLA EC® safely and effectively. See full prescribing information for THIOLA EC.

THIOLA EC (tiopronin) delayed-release tablets, for oral use

Initial U.S. Approval: 1988

----------RECENT MAJOR CHANGES----------

Dosage and Administration (2.2) 03/2021

----------INDICATIONS AND USAGE----------

THIOLA EC 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 20 kg and greater with severe homozygous cystinuria, who are not responsive to these measures alone. (1)

----------DOSAGE AND ADMINISTRATION----------

- The recommended initial dosage in adult patients is 800 mg/day. In clinical studies, the average dosage was about 1,000 mg/day. (2.1)
- The recommended initial dosage in pediatric patients 20 kg and greater is 15 mg/kg/day. Avoid dosages greater than 50 mg/kg per day in pediatric patients. (5.1, 8.4)
- Measure urinary cystine 1 month after initiation of THIOLA EC and every 3 months thereafter (2.3)
- Administer THIOLA EC in 3 divided doses at the same times each day, with or without food. Maintain a routine pattern with regard to meals. (2.1)
- THIOLA EC can be crushed and mixed with applesauce. For preparation and administration instructions, see the full prescribing information. (2.2))

----------DOSAGE FORMS AND STRENGTHS----------

Tablets: 100 mg and 300 mg (3)

----------CONTRAINDICATIONS----------

- Hypersensitivity to tiopronin or any component of THIOLA EC (4)

----------WARNINGS AND PRECAUTIONS----------

- Proteinuria, including nephrotic syndrome, and membranous nephropathy, has been reported with tiopronin use. Pediatric patients receiving greater than 50 mg/kg of tiopronin per day may be at increased risk for proteinuria. (2.1, 5.1, 8.4)
- Hypersensitivity reactions have been reported during tiopronin treatment. (4, 5.2)

----------ADVERSE REACTIONS----------

Most common adverse reactions (≥10%) are nausea, diarrhea or soft stools, oral ulcers, rash, fatigue, fever, arthralgia, proteinuria, and emesis. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Mission Pharmacal Company at toll-free phone # 1-800-298-1087 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------USE IN SPECIFIC POPULATIONS----------

- Lactation: Breastfeeding is not recommended. (8.2)
- Geriatric: Choose dose carefully and monitor renal function in the elderly. (8.5)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 03/2021

FULL PRESCRIBING INFORMATION: CONTENTS*

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* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

THIOLA EC is indicated, in combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria, who are not responsive to these measures alone.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

Adults: The recommended initial dosage in adult patients is 800 mg/day. In clinical studies, the average dosage was about 1,000 mg/day.

Pediatrics: The recommended initial dosage in pediatric patients weighing 20 kg and greater is 15 mg/kg/day. Avoid dosages greater than 50 mg/kg per day in pediatric patients *[see Warnings and Precautions (5.1), Use in Specific Populations (8.4)]*.

Administer THIOLA EC in 3 divided doses at the same times each day, with or without food. Maintain a routine pattern with regard to meals.

Consider starting THIOLA EC at a lower dosage in patients with history of severe toxicity to d-penicillamine.

2.2 Preparation and Administration Instructions

For patients who cannot swallow the tablet whole, THIOLA EC can be crushed and mixed with applesauce. Administration of THIOLA EC with other liquids or foods has not been studied and is not recommended.

Preparation and Administration of THIOLA EC Mixed in Applesauce

For patients who can swallow semi-solid food, THIOLA EC can be crushed and mixed with applesauce:

1. Crush the THIOLA EC tablet in a clean pill crusher or mortar and pestle. Always crush one tablet at a time.
2. Measure approximately one tablespoon of applesauce and transfer it into a container with the crushed THIOLA EC tablet.
3. Mix the crushed THIOLA EC tablet in the applesauce until the powder is well dispersed.
4. Administer the entire THIOLA EC-applesauce mixture to the patient's mouth immediately. (However, if this is not possible, the mixture can be stored in a refrigerator for up to 2 hours after adding the crushed tablet to the applesauce. Discard any mixture that has not been given within 2 hours.)
5. To assure that any leftover applesauce mixture from the container is recovered, add tap water to the same container, mix, and have the patient drink the water.

2.3 Monitoring

Measure urinary cystine 1 month after starting THIOLA EC and every 3 months thereafter. Adjust THIOLA EC dosage to maintain urinary cystine concentration less than 250 mg/L.

Assess for proteinuria before treatment and every 3 to 6 months during treatment *[see Warnings and Precautions (5.1)]*.

Discontinue THIOLA EC in patients who develop proteinuria, and monitor urinary protein and renal function. Consider restarting THIOLA EC treatment at a lower dosage after resolution of proteinuria.

3 DOSAGE FORMS AND STRENGTHS

Tablets for oral use:
100 mg tablets: round, white to off-white and imprinted in red with "T1" on one side
300 mg tablets: round, white to off-white and imprinted in red with "T3" on one side

4 CONTRAINDICATIONS

THIOLA EC is contraindicated in patients with hypersensitivity to tiopronin or any other components of THIOLA EC *[see Warnings and Precautions (5.2)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Proteinuria

Proteinuria, including nephrotic syndrome, and membranous nephropathy, have been reported with tiopronin use. Pediatric patients receiving greater than 50 mg/kg of tiopronin per day may be at increased risk for proteinuria. *[see Dosage and Administration (2.3), Adverse Reactions (6.1, 6.2) Use in Specific Populations (8.4)]*. Monitor patients for the development of proteinuria and discontinue therapy in patients who develop proteinuria *[see Dosage and Administration (2.3)]*.

5.2 Hypersensitivity Reactions

Hypersensitivity reactions (drug fever, rash, fever, arthralgia and lymphadenopathy) have been reported *[see Contraindications (4)]*.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Proteinuria *[see Warnings and Precautions (5.1)]*
- Hypersensitivity *[see Warnings and Precautions (5.2)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed in the clinical trials of the drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Adverse reactions occurring at an incidence of ≥5% in an uncontrolled trial in 66 patients with cystinuria age 9 to 68 years are shown in the table below. Patients in group 1 had previously been treated with d-penicillamine; those in group 2 had not. Of those patients who had stopped taking d-penicillamine due to toxicity (34 out of 49 patients in group 1), 22 were able to continue treatment with THIOLA. In those without prior history of d-penicillamine treatment, 6% developed reactions of sufficient severity to require THIOLA withdrawal.

Table 1 presents adverse reactions ≥5% in either treatment group occurring in this trial.

Table 1: Adverse Reactions Occurring in One or More Patients

System Organ Class	Adverse Reaction	Group 1 Previously treated with d-penicillamine (N = 49)	Group 2 Naïve to d-penicillamine (N = 17)
Blood and Lymphatic System Disorders	anemia	1 (2%)	1 (6%)
Gastrointestinal Disorders	nausea	12 (25%)	2 (12%)
	emesis	5 (10%)	–
	diarrhea/soft stools	9 (18%)	1 (6%)
	abdominal pain	–	1 (6%)
	oral ulcers	6 (12%)	3 (18%)
General Disorders and Administration Site Conditions	fever	4 (8%)	–
	weakness	2 (4%)	2 (12%)
	fatigue	7 (14%)	–
	peripheral (edema)	3 (6%)	1 (6%)
	chest pain	–	1 (6%)
Metabolism and Nutrition Disorders	anorexia	4 (8%)	–
Musculoskeletal and Connective Tissue Disorders	arthralgia	–	2 (12%)
Renal and Urinary Disorders	proteinuria	5 (10%)	1 (6%)
	impotence	–	1 (6%)
Respiratory, Thoracic and Mediastinal Disorders	cough	–	1 (6%)
Skin and Subcutaneous Tissue Disorders	rash	7 (14%)	2 (12%)
	ecchymosis	3 (6%)	–
	pruritus	2 (4%)	1 (6%)
	urticaria	4 (8%)	–
	skin wrinkling	3 (6%)	1 (6%)

Taste Disturbance
A reduction in taste perception may develop. It is believed to be the result of chelation of trace metals by tiopronin. Hypogeusia is often self-limited.

6.2 Postmarketing Experience
Adverse reactions have been reported from the literature, as well as during post-approval use of THIOLA. Because the post-approval reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to THIOLA exposure.

Adverse reactions reported during the postmarketing use of THIOLA are listed by body system in **Table 2.**

Table 2: Adverse Reactions Reported for THIOLA Pharmacovigilance by System Organ Class and Preferred Term

System Organ Class	Preferred Term
Cardiac Disorders	congestive heart failure
Ear and Labyrinth Disorder	vertigo
Gastrointestinal Disorders	abdominal discomfort; abdominal distension; abdominal pain; chapped lips; diarrhea; dry mouth; dyspepsia; eructation; flatulence; gastrointestinal disorder; gastroesophageal reflux disease; nausea; vomiting; jaundice; liver transaminitis
General Disorders and Administration Site Conditions	asthenia; chest pain; fatigue; malaise; pain; peripheral swelling; pyrexia; swelling
Investigations	glomerular filtration rate decreased; weight increased
Metabolism and Nutrition Disorders	decreased appetite; dehydration; hypophagia
Musculoskeletal and Connective Tissue Disorders	arthralgia; back pain; flank pain; joint swelling; limb discomfort; musculoskeletal discomfort; myalgia; neck pain; pain in extremity
Nervous System Disorders	ageusia; burning sensation; dizziness; dysgeusia; headache; hypoesthesia
Renal and Urinary Disorders	nephrotic syndrome; proteinuria; renal failure
Skin and Subcutaneous Tissue Disorders	dry skin; hyperhidrosis; pemphigus foliaceus; pruritus; rash; rash pruritic; skin irritation; skin texture abnormal; skin wrinkling; urticaria

7 DRUG INTERACTIONS
7.1 Alcohol
Tiopronin is released faster from THIOLA EC in the presence of alcohol and the risk for adverse events associated with THIOLA EC when taken with alcohol is unknown. Avoid alcohol consumption 2 hours before and 3 hours after taking THIOLA EC *[see Clinical Pharmacology (12.3)].*

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Risk Summary
Available published case report data with tiopronin have not identified a drug-associated risk for major birth defects, miscarriage, or adverse maternal or fetal outcomes. Renal stones in pregnancy may result in adverse pregnancy outcomes *(see Clinical Considerations).* In animal reproduction studies, there were no adverse developmental outcomes with oral administration of tiopronin to pregnant mice and rats during organogenesis at doses up to 2 times a 2 grams/day human dose (based on mg/m^2). The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies are 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-associated maternal and/or embryo/fetal risk
Renal stones in pregnancy may increase the risk of adverse pregnancy outcomes, such as preterm birth and low birth weight.

Data

Animal Data
No findings of fetal malformations could be attributed to the drug in reproduction studies in mice and rats at doses up to 2 times the highest recommended human dose of 2 grams/day (based on mg/m^2).

8.2 Lactation
Risk Summary
There are no data on the presence of tiopronin in either human or animal milk or on the effects of the breastfed child. A published study suggests that tiopronin may suppress milk production. Because of the potential for serious adverse reactions, including nephrotic syndrome, advise patients that breastfeeding is not recommended during treatment with THIOLA EC.

8.4 Pediatric Use
THIOLA EC is indicated in pediatric patients weighing 20 kg or more with severe homozygous cystinuria, in combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation who are not responsive to these measures alone. This indication is based on safety and efficacy data from a trial in patients 9 years to 68 years of age and clinical experience. Proteinuria, including nephrotic syndrome, has been reported in pediatric patients. Pediatric patients receiving greater than 50 mg/kg tiopronin per day may be at greater risk *[see Dosage and Administration (2.1, 2.3), Warnings and Precautions (5.1)* and *Adverse Reactions (6.1)].*

THIOLA EC tablets are not approved for use in pediatric patients weighing less than 20 kg *[see Dosage and Administration (2.1)].*

8.5 Geriatric Use
This drug is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

10 OVERDOSAGE
There is no information on overdosage with tiopronin.

11 DESCRIPTION
THIOLA EC (tiopronin) delayed-release tablets are a reducing and cystine-binding thiol drug (CBTD) for oral use. Tiopronin is N-(2-Mercaptopropionyl) glycine and has the following structure:

Tiopronin has the empirical formula $C_5H_9NO_3S$ and a molecular weight of 163.20. In this drug product tiopronin exists as a dl racemic mixture.

Tiopronin is a white crystalline powder, which is freely soluble in water.

Each THIOLA EC tablet contains 100 or 300 mg of tiopronin. The inactive ingredients in THIOLA EC tablets include lactose monohydrate, hydroxypropyl cellulose, hydroxypropyl cellulose (low substitute), magnesium stearate, hydroxypropyl methylcellulose E5, methacrylic acid: ethyl acrylate copolymer (Eudragit L 100-55), talc, triethyl citrate.

12 CLINICAL PHARMACOLOGY
12.1 Mechanism 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.

12.2 Pharmacodynamics
The decrement in urinary cystine produced by tiopronin is generally proportional to the dose. A reduction in urinary cystine of 250-350 mg/day at tiopronin dosage of 1 g/day, and a decline of approximately 500 mg/day at a dosage of 2 g/day, might be expected. Tiopronin has a rapid onset and offset of action, showing a fall in cystine excretion on the first day of administration and a rise on the first day of drug withdrawal.

12.3 Pharmacokinetics
Absorption

THIOLA EC Tablets
When THIOLA IR and THIOLA EC single doses were given to fasted healthy subjects, the median time to peak plasma levels (T_{max}) was 1 (range: 0.5 to 2.1) and 3 (range: 1.0 to 6.0) hours, respectively. The peak exposure (C_{max}) and total exposure (AUC_{0-t}) of tiopronin from THIOLA EC tablets were decreased by 22% and 7% respectively compared to THIOLA IR tablets.

When THIOLA EC tablets were administered crushed in applesauce, the median time to peak plasma levels of tiopronin (T_{max}) was 1 hour (range: 0.5 to 2.0) compared to 3.1 hours (range: 1.5 to 4.0) when administered as intact EC tablets.

When THIOLA EC tablets were administered crushed in applesauce, the maximum concentration (C_{max}) and exposure (AUC_{0-t}) to tiopronin were increased by 38% and 14%, respectively, compared to THIOLA EC tablets administered intact.

Food Effects
Administration of the THIOLA EC tablet with food decreases C_{max} of tiopronin by 13% and AUC_{0-t} by 25% compared to THIOLA EC administered in a fasted state.

Since the drug is dosed to effect, the study results support administration of THIOLA EC tablets with or without food; administer at the same time each day with a routine pattern with regard to meals.

Elimination

Excretion
When tiopronin is given orally, up to 48% of dose appears in urine during the first 4 hours and up to 78% by 72 hours.

Drug Interactions

Alcohol
An *in vitro* dissolution study was conducted to evaluate the impact of alcohol (5, 10, 20, and 40%) on the dose dumping of THIOLA EC tablets. The study results showed that the addition of alcohol to the dissolution media increases the dissolution rate of THIOLA EC tablets in the acidic media of 0.1N HCl *[see Drug Interactions (7.1)].*

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis
Long-term carcinogenicity studies in animals have not been performed.

Mutagenesis
Tiopronin was not genotoxic in the chromosomal aberration, sister chromatid exchange, and *in vivo* micronucleus assays.

Impairment of Fertility
High doses of tiopronin in experimental animals have been shown to interfere with maintenance of pregnancy and viability of the fetus. In 2 published male fertility studies in rats, tiopronin at 20 mg/kg/day intramuscular (IM) for 60 days induced reductions in testis, epididymis, vas deferens, and accessory sex glands weights and in the count and motility of cauda epididymal sperm.

16 HOW SUPPLIED/STORAGE AND HANDLING
100 mg delayed-release, round, white to off-white tablet imprinted with “T1” on one side with red ink and blank on the other side: Bottles of 300 **NDC** 0178-0902-01.

300 mg delayed-release, round, white to off-white tablet imprinted with “T3” on one side with red ink and blank on the other side: Bottles of 90 **NDC** 0178-0901-90.

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) *[see USP Controlled Room Temperature].*

17 PATIENT COUNSELING INFORMATION
Administration Instructions
For patients who cannot swallow the tablet whole, the THIOLA EC tablets can be crushed and mixed with applesauce. *See Dosage and Administration (2.2)* for preparation and administration instructions.

Lactation
Advise women that breastfeeding is not recommended during treatment with THIOLA EC *[see Use in Specific Populations (8.2)].*

L090201R0824

Mission® PHARMACAL

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Distributed by Travere Therapeutics, Inc., San Diego, CA 92130