Tonmya™
(cyclobenzaprine HCl)
sublingual tablets 2.8mg

NOW APPROVED

FOR THE TREATMENT OF FIBROMYALGIA IN ADULTS

TONMYA is the first FDA-approved therapy for the treatment of fibromyalgia in over 15 years.[1-4]

TONMYA is expected to be available in the fourth quarter of this year.

TONMYA demonstrated sustained improvement in fibromyalgia's core symptoms of widespread pain, sleep disturbance, and fatigue in the RESILIENT trial[1,5*†‡]

PRIMARY ENDPOINT:

- **NRS Pain Score change from baseline to Week 14:** Statistically significant vs placebo (-1.8 vs -1.2, p<0.001)[5]

SELECT KEY SECONDARY ENDPOINTS:

- **FIQ-R Function Domain:** Statistically significant change from baseline vs placebo at Week 14 (-12.2 vs -6.8, p=0.001)[6]
- **PROMIS Sleep Disturbance:** Statistically significant change from baseline vs placebo at Week 14 (-8.4 vs -4.2, p<0.001)[5]
- **Sleep Quality NRS:** Statistically significant from baseline vs placebo at Week 14 (-1.8 vs -1.2, p<0.001)[6]
- **PROMIS Fatigue:** Statistically significant from baseline vs placebo at Week 14 (-7.2 vs -4.2, p<0.001)[5]

*RESILIENT was a randomized, double-blind, phase 3 study in 457 patients with fibromyalgia who were randomized to receive TONMYA (n=231) or placebo (n=226) for 14 weeks. A single placebo subject was randomized in error and was excluded from the ITT population (defined as all randomized patients who took at least 1 dose of study drug and had at least 1 post-baseline assessment). The safety population consisted of all 457 patients who received at least 1 dose of study drug. All endpoints reported as LS mean change from baseline.[1,5]

†The RELIEF study was identical in protocol to the RESILIENT study and met its primary endpoint (change from baseline in average daily pain at Week 14). The secondary endpoints were evaluated sequentially and the first endpoint did not meet statistical significance and therefore all secondary endpoints are considered descriptive.[7]

‡The RALLY study was identical in protocol to RESILIENT and there was no statistically significant treatment group difference between TONMYA and placebo on the primary endpoint. Results of this trial may not have been generalizable due to the presence of factors outside the conduct of the study.[1]

INDICATION

TONMYA is indicated for the treatment of fibromyalgia in adults.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

TONMYA is contraindicated:

- In patients with hypersensitivity to cyclobenzaprine or any inactive ingredient in TONMYA. Hypersensitivity reactions may manifest as an anaphylactic reaction, urticaria, facial and/or tongue swelling, or pruritus. Discontinue TONMYA if a hypersensitivity reaction is suspected.
- With concomitant use of monoamine oxidase (MAO) inhibitors or within 14 days after discontinuation of an MAO inhibitor. Hyperpyretic crisis seizures and deaths have occurred in patients who received cyclobenzaprine (or structurally similar tricyclic antidepressants) concomitantly with MAO inhibitors drugs.
- During the acute recovery phase of myocardial infarction, and in patients with arrhythmias, heart block or conduction disturbances, or congestive heart failure.
- In patients with hyperthyroidism.

Please see additional Important Safety Information on the next pages and full Prescribing Information.

FIQ-R, Fibromyalgia Impact Questionnaire-Revised; ITT, intent to treat; LS, least squares; NRS, numerical rating scale; PROMIS, Patient-reported Outcomes Measurement Information System.

TONMYA may be the treatment your patients have been waiting for

ESTABLISHED SAFETY PROFILE

- Most common adverse reactions (incidence ≥2% and at a higher incidence in TONMYA-treated patients compared to placebo-treated patients): oral hypoesthesia, oral discomfort, abnormal product taste, somnolence, oral paresthesia, oral pain, fatigue, dry mouth, and aphthous ulcer[1]
- Weight gain and blood pressure were similar to placebo. There were no reports of cognitive dysfunction or sexual dysfunction [1,5,8]

UNIQUE SUBLINGUAL FORMULATION ALLOWS FOR RAPID ABSORPTION AT BEDTIME AND AVOIDS FIRST-PASS HEPATIC METABOLISM[1,5]

Administered sublingually as follows:

DAYS 1–14

Starting Dose
Days 1 to 14:
2.8 mg (1 tablet) once daily at bedtime

DAYS 15+

Target Dose
Day 15 and daily thereafter:
5.6 mg (2 tablets; the maximum recommended dosage) once daily at bedtime

Administration in specific populations:

- In geriatric patients and patients with mild hepatic impairment, a 2.8 mg dose (1 tablet; the maximum recommended dosage) administered under the tongue once daily at bedtime is recommended. **The use of TONMYA is not recommended in patients with moderate or severe hepatic impairment**
- **Pregnancy testing is recommended in females of reproductive potential prior to initiating treatment with TONMYA**

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

- **Embryofetal toxicity:** Based on animal data, TONMYA may cause neural tube defects when used two weeks prior to conception and during the first trimester of pregnancy. Advise females of reproductive potential of the potential risk and to use effective contraception during treatment and for two weeks after the final dose. Perform a pregnancy test prior to initiation of treatment with TONMYA to exclude use of TONMYA during the first trimester of pregnancy.
- **Serotonin syndrome:** Concomitant use of TONMYA with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, tramadol, bupropion, meperidine, verapamil, or MAO inhibitors increases the risk of serotonin syndrome, a potentially life-threatening condition. Serotonin syndrome symptoms may include mental status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms. Treatment with TONMYA and any concomitant serotonergic agent should be discontinued immediately if serotonin syndrome symptoms occur and supportive symptomatic treatment should be initiated. If concomitant treatment with TONMYA and other serotonergic drugs is clinically warranted, careful observation is advised, particularly during treatment initiation or dosage increases.
- **Tricyclic antidepressant-like adverse reactions:** Cyclobenzaprine is structurally related to TCAs. TCAs have been reported to produce arrhythmias, sinus tachycardia, prolongation of the conduction time leading to myocardial infarction and stroke. If clinically significant central nervous system (CNS) symptoms develop, consider discontinuation of TONMYA. Caution should be used when TCAs are given to patients with a history of seizure disorder, because TCAs may lower the seizure threshold. Patients with a history of seizures should be monitored during TCA use to identify recurrence of seizures or an increase in the frequency of seizures.
- **Atropine-like effects:** Use with caution in patients with a history of urinary retention, angle-closure glaucoma, increased intraocular pressure, and in patients taking anticholinergic drugs.
- **CNS depression and risk of operating a motor vehicle or hazardous machinery:** TONMYA monotherapy may cause CNS depression. Concomitant use of TONMYA with alcohol, barbiturates, or other CNS depressants may increase the risk of CNS depression. Advise patients not to operate a motor vehicle or dangerous machinery until they are reasonably certain that TONMYA therapy will not adversely affect their ability to engage in such activities.
- **Oral mucosal adverse reactions:** In clinical studies with TONMYA, oral mucosal adverse reactions occurred more frequently in patients treated with TONMYA compared to placebo. Advise patients to moisten the mouth with sips of water before administration of TONMYA to reduce the risk of oral sensory changes (hypoesthesia). Consider discontinuation of TONMYA if severe reactions occur.

Please see additional Important Safety Information on the next and previous pages and full Prescribing Information.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥2% and at a higher incidence in TONMYA-treated patients compared to placebo-treated patients) were oral hypoesthesia, oral discomfort, abnormal product taste, somnolence, oral paresthesia, oral pain, fatigue, dry mouth, and aphthous ulcer.

DRUG INTERACTIONS

- MAO inhibitors: Life-threatening interactions may occur.
- Other serotonergic drugs: Serotonin syndrome has been reported.
- CNS depressants: CNS depressant effects of alcohol, barbiturates, and other CNS depressants may be enhanced.
- Tramadol: Seizure risk may be enhanced.
- Guanethidine or other similar acting drugs: The antihypertensive action of these drugs may be blocked.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Based on animal data, TONMYA may cause fetal harm when administered to a pregnant woman. The limited amount of available observational data on oral cyclobenzaprine use in pregnancy is of insufficient quality to inform a TONMYA-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Advise pregnant women about the potential risk to the fetus with maternal exposure to TONMYA and to avoid use of TONMYA two weeks prior to conception and through the first trimester of pregnancy. Report pregnancies to the Tonix Medicines, Inc., adverse-event reporting line at 1-888-869-7633 (1-888-TNXPMED).
- **Lactation:** A small number of published cases report the transfer of cyclobenzaprine into human milk in low amounts, but these data cannot be confirmed. There are no data on the effects of cyclobenzaprine on a breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TONMYA and any potential adverse effects on the breastfed child from TONMYA or from the underlying maternal condition.
- **Pediatric use:** The safety and effectiveness of TONMYA have not been established.
- **Geriatric patients:** Of the total number of TONMYA-treated patients in the clinical trials in adult patients with fibromyalgia, none were 65 years of age and older. Clinical trials of TONMYA did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger adult patients.
- **Hepatic impairment:** The recommended dosage of TONMYA in patients with mild hepatic impairment (HI) (Child Pugh A) is 2.8 mg once daily at bedtime, lower than the recommended dosage in patients with normal hepatic function. The use of TONMYA is not recommended in patients with moderate HI (Child Pugh B) or severe HI (Child Pugh C). Cyclobenzaprine exposure (AUC) was increased in patients with mild HI and moderate HI compared to subjects with normal hepatic function, which may increase the risk of TONMYA-associated adverse reactions.

Please see additional safety information in the full Prescribing Information.

To report suspected adverse reactions, contact Tonix Medicines, Inc. at 1-888-869-7633, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information on the previous pages and full Prescribing Information.

References: 1. TONMYA™ (cyclobenzaprine HCl) [prescribing information]. Chatham, NJ: Tonix Medicines, Inc.; 2025. **2.** LYRICA® (pregabalin) [prescribing information]. Morgantown, WV: Viatris Specialty, LLC, a Viatris Company; 2025. **3.** CYMBALTA® (duloxetine delayed-release capsules) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; 2023. **4.** SAVELLA® (milnacipran HCl) [prescribing information]. Chicago, IL: Allergan Sales, LLC, an AbbVie company; 2023. **5.** Lederman S, et al. *Pain Medicine*, 2025; pnaf089, doi:10.1093/pm/pnaf089 **6.** Lederman S, et al. [Supplemental]. *Pain Medicine*, 2025; pnaf089, doi:10.1093/pm/pnaf089. **7.** Lederman S, et al. *Arthritis Care & Res*. 2023;75(11):2359-2368. **8.** Data on File, Tonix Medicines, Inc.

TONIX MEDICINES

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