UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (date of earliest event reported): August 15, 2025

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada	**001-36019**	**26-1434750**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

26 Main Street, Chatham, New Jersey 07928
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(862) 799-8599**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	TNXP	The NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On August 15, 2025, Tonix Pharmaceuticals Holding Corp. (the "Company") announced that the U.S. Food and Drug Administration ("FDA") approved Tonmya™ (cyclobenzaprine HCl sublingual tablets), which was investigated as TNX-102 SL, for the treatment of fibromyalgia in adults. Tonmya is expected to be available for adult patients in the U.S. with fibromyalgia beginning in the fourth quarter of 2025. A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, and incorporated herein by reference.

The Company will host a webcast and conference call on August 18, 2025 at 8:30 a.m. Eastern Time to discuss the approval. Instructions on how to access the webcast and conference call are included in the press release furnished as Exhibit 99.1 hereto.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On August 15, 2025, the Company announced that the FDA approved Tonmya for the treatment of fibromyalgia in adults. Tonmya is expected to be available for adult patients in the U.S. with fibromyalgia beginning in the fourth quarter of 2025. The approval incorporated efficacy data from two double-blind, randomized, placebo-controlled, Phase 3 clinical trials of an aggregate of 1,000 patients that evaluated Tonmya as a bedtime treatment for fibromyalgia. Across both Phase 3 trials, Tonmya significantly reduced daily pain scores compared to placebo at 14 weeks, the primary endpoint. Additionally, a greater percentage of study participants taking Tonmya experienced a clinically meaningful (≥30%) improvement in their pain after three months, compared to placebo. Across three Phase 3 clinical trials with over 1,400 patients evaluated, Tonmya was generally well tolerated. The most common adverse events (incidence ≥2% and at a higher incidence in Tonmya-treated patients compared to placebo-treated patients) included oral hypoesthesia, oral discomfort, abnormal product taste, somnolence, oral pain, fatigue, dry mouth and aphthous ulcer.

IMPORTANT SAFETY INFORMATION

INDICATION
TONMYA is indicated for the treatment of fibromyalgia in adults.

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.

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.

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.

Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the SEC. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Press Release of the Company, dated August 15, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: August 15, 2025

By: /s/ Bradley Saenger
Bradley Saenger
Chief Financial Officer

Exhibit 99.01

Tonix Pharmaceuticals Announces FDA Approval of Tonmya™ (cyclobenzaprine HCl sublingual tablets) for the Treatment of Fibromyalgia

Tonmya is the first FDA-approved therapy for the treatment of fibromyalgia in over 15 years

Fibromyalgia is a chronic pain condition that affects more than 10 million adults in the U.S. who are mostly women

Two Pivotal Phase 3 studies demonstrated Tonmya significantly reduced fibromyalgia pain compared to placebo; generally well tolerated

Commercial availability of Tonmya is expected in the fourth quarter

Company to host webcast and conference call on Monday August 18, 2025 at 8:30 AM ET

CHATHAM, N.J., August 15, 2025 (GLOBE NEWSWIRE) --Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a fully-integrated biotechnology company, today announced that the U.S. Food and Drug Administration (FDA) approved Tonmya™ (cyclobenzaprine HCl sublingual tablets) for the treatment of fibromyalgia in adults. Tonmya is a first-in-class, non-opioid, once-daily bedtime analgesic with a unique sublingual (under the tongue) formulation that is designed for rapid absorption into the bloodstream. Tonmya is the first new FDA-approved therapy for the treatment of fibromyalgia in over 15 years.

“The FDA approval of Tonmya as a first-line treatment for fibromyalgia represents a landmark advancement for the millions of people in the U.S. suffering from the debilitating pain this condition causes,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “At Tonix, we recognized the transformative potential of pursuing a new approach with Tonmya for fibromyalgia, a chronic overlapping pain condition (COPC), that has gone without innovation for many years. We are hopeful that effectively treating pain with Tonmya could help improve the lives of people with this chronic syndrome.”

“The chronic pain of fibromyalgia is debilitating to every aspect of a person’s life, including causing sleep disturbance and fatigue, all of which can negatively impact someone’s ability to carry out their daily activities,” said Sharon Waldrop, a person with lived experience and founder of the Fibromyalgia Association. “For over 15 years, this community has been underserved and waiting for new treatment options. This approval is a promising step forward and brings renewed hope to millions.”

The approval incorporated efficacy from two double-blind, randomized, placebo-controlled, Phase 3 clinical trials of nearly 1,000 patients in total that evaluated Tonmya as a bedtime treatment for fibromyalgia. Across both Phase 3 trials, Tonmya significantly reduced daily pain scores compared to placebo at 14 weeks, the primary endpoint. Additionally, a greater percentage of study participants taking Tonmya experienced a clinically meaningful (30%) improvement in their pain after three months, compared to placebo.

Across three Phase 3 clinical trials with over 1,400 patients evaluated, Tonmya was generally well tolerated. The most common adverse events (incidence ≥2% and at a higher incidence in Tonmya-treated patients compared to placebo-treated patients) included oral hypoesthesia (numbness in the mouth), oral discomfort, abnormal product taste, somnolence (drowsiness), oral paresthesia (tingling, pricking or burning in the mouth), oral pain, fatigue, dry mouth, and aphthous ulcer (canker sore).

“For many years, rheumatologists like myself and other healthcare professionals have had to manage fibromyalgia with limited options that do not adequately meet treatment needs for the majority of patients,” said Philip Mease, M.D., Director of Rheumatology Research at the Providence Swedish Medical Center and Clinical Professor at the University of Washington School of Medicine. “Tonmya is a novel treatment approach that targets nonrestorative sleep that is characteristic of fibromyalgia and can impact core symptoms, specifically pain.”

The latest Phase 3 trial, RESILIENT, was recently published in *Pain Medicine* with data on primary and secondary endpoints measuring pain, patient's global impression of change, patient-reported symptoms and function, sleep disturbance, and fatigue.

"I know firsthand how the chronic pain of fibromyalgia significantly disrupts my patients' lives." Andrea L. Chadwick, M.D., MSc, FASA, Anesthesiology, Pain, and Perioperative Medicine at The University of Kansas Health System. "Treatments that are processed through the liver can result in metabolites that could affect a medicine's efficacy and safety over time. Tonmya is administered sublingually which is designed to reduce pain quickly and durably with a tolerable safety profile."

Tonix thanks the participants and investigators involved in its fibromyalgia clinical trials, and FDA for its commitment to approving new treatments for this condition.

Tonmya is expected to be available for adult patients in the U.S. with fibromyalgia beginning in the fourth quarter of this year.

For more information, visit TonmyaHCP.com or download the TONMYA Fact Sheet here.

Webcast Information

Tonix will host a webcast and conference call on Monday, August 18 at 8:30 AM ET to discuss the approval of Tonmya. The live webcast of the call will be available on the Investors section of Tonix's website: https://ir.tonixpharma.com/news-events/ir-events. To participate by phone, please register in advance using this link to obtain a local or toll-free phone number and your personal pin. A replay of the webcast will be available for approximately 90 days following the live event. The slides presented during the webcast will be made available on the "Presentations" page of the "Investors" section of the Company's website.

About Fibromyalgia

Fibromyalgia is a chronic pain disorder that is understood to result from amplified sensory and pain signaling within the central nervous system. Fibromyalgia afflicts an estimated 10 million adults in the U.S., approximately 80% of whom are women. Symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep (waking up tired and unrefreshed), fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life, and frequently are disabled. Patients with fibromyalgia have double the medical costs compared to the general population in the U.S.

About Tonmya™ (cyclobenzaprine HCl sublingual tablets)

Tonmya, which was investigated as TNX-102 SL, is a patented sublingual tablet formulation of cyclobenzaprine hydrochloride, which provides rapid transmucosal absorption and reduced production of a long half-life active metabolite, norcyclobenzaprine, due to bypass of first-pass hepatic metabolism. As a tertiary amine tricyclic (TAT) and multifunctional agent with potent binding and antagonist activities at the 5-HT2A serotonergic, α1-adrenergic, H1-histaminergic, and M1-muscarinic receptors, Tonmya is now approved as a once-daily bedtime treatment for fibromyalgia in adults. The United States Patent and Trademark Office (USPTO) issued United States Patent No. 9636408 in May 2017, Patent No. 9956188 in May 2018, Patent No. 10117936 in November 2018, Patent No. 10357465 in July 2019, and Patent No. 10736859 in August 2020. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the patent are important elements of Tonix's proprietary composition. These patents are expected to provide Tonmya with U.S. market exclusivity until 2034. Pending patent applications related to method of use could extend exclusivity until 2044.

About the Phase 3 Clinical Trials: RELIEF and RESILIENT

The RELIEF and RESILIENT studies were double-blind, randomized, placebo-controlled trials designed to evaluate the efficacy and safety of Tonmya™ (cyclobenzaprine hydrochloride sublingual tablets) for the treatment of fibromyalgia. RELIEF and RESILIENT were two-arm trials that enrolled 503 and 457 adults with fibromyalgia across 40 and 33 United States sites, respectively. In both trials, the first two weeks of treatment consisted of a run-in period in which participants started on Tonmya 2.8 mg (1 tablet) or placebo. Thereafter, all participants increased their dose to Tonmya 5.6 mg (2 x 2.8 mg tablets) or two placebo tablets for the remaining 12 weeks. The primary endpoint across both trials was the daily diary pain intensity score change (Tonmya 5.6 mg vs. placebo) from baseline to Week 14 (using the weekly averages of the daily numerical rating scale scores). Additional details on RELIEF (NCT04172831) and RESILIENT (NCT05273749) are available on clinicaltrials.gov.

RALLY was a replicate Phase 3 trial to RELIEF and RESILIENT that demonstrated greater but non-significant treatment effect with Tonmya compared to placebo and demonstrated consistent safety. Results of this trial may not have been generalizable due to the presence of factors outside the conduct of the study. Additional details are available on clinicaltrials.gov (NCT04508621).

Tonix Pharmaceuticals Holding Corp.

Tonix is a fully-integrated biotechnology company. Tonix's development portfolio is focused on central nervous system (CNS) disorders, immunology, immuno-oncology and infectious diseases. Tonix owns and operates a state-of-the art infectious disease research facility in Frederick, MD. Tonix Medicines, Inc., our wholly-owned commercial subsidiary, markets treatments for fibromyalgia and acute migraine.

This press release and further information about Tonix can be found at www.tonixpharma.com.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the failure to successfully market any of our products; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2024, as filed with the Securities and Exchange Commission (the "SEC") on March 18, 2025, and periodic reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

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INDICATION

TONMYA is indicated for the treatment of fibromyalgia in adults.

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.

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.

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.

Source: Tonix Pharmaceuticals Holding Corp.

Released August 15, 2025