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): **December 29, 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 December 29, 2025, Tonix Pharmaceuticals Holding Corp. (the "Company") announced program updates on its TNX-4800 product candidate for protection against Lyme disease. A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, and incorporated herein by reference.

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 December 29, 2025, the Company announced that it plans to meet with the U.S. Food and Drug Administration ("FDA") in 2026 to explore Phase 2/3 development options for TNX-4800. The Company believes that a controlled human infection model study using *Borrelia*-infected ticks that mimic natural infection would be a potential path to demonstrating TNX 4800 efficacy for potential FDA approval, and that it may have investigational product produced under Good Manufacturing Practices (GMP) available for testing early in 2027. The Company further believes that (i) prophylaxis with TNX-4800 may avoid the limitations of vaccine products designed to actively immunize against Lyme disease, including suboptimal immune responses from age, immunocompetence, and other reasons, and (ii) protection against *Borrelia* will require annual prophylaxis as exposed or infected individuals rarely make antibodies against the outer surface protein A (OspA) of *Borrelia burgdorferi*, the causative agent of Lyme disease in humans.

TNX-4800 was studied in a randomized, double-blind, sequential dose-escalation study that evaluated safety, tolerability, pharmacokinetics ("PK"), and immunogenicity of TNX-4800 in healthy adults. Forty-four subjects were randomized and 41 completed the study. Subjects received a single subcutaneous administration of placebo or TNX-4800 at 0.5, 1.5, 5, or 10 mg/kg. Safety was assessed by clinical and lab evaluations. Drug exposure increased 25 times, for a 20 times increase in dose. Serum TNX-4800 was measurable at the earliest sampling time of 24 hours, indicating rapid systemic absorption. TNX-4800 concentrations remained quantifiable for more than 200 days in 80% of volunteers at the lowest dose, and for up to 350 days in the majority of volunteers at higher doses (i.e., $\geq$ 1.5 mg/kg). Mean half-life ranged from 62 to 69 days across groups. Serum concentrations remained quantifiable for up to 12 months in most subjects. Mean exposure for the 10 mg/kg cohort was less than 20% of the highest exposures in a rat toxicology study. Anti-drug antibodies were detected in less than 10% of treated subjects, with no impact on PK. Most adverse events were mild or moderate. TNX-4800 was determined to be generally safe and well tolerated.

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, December 29, 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: December 29, 2025

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Program Updates on Phase 2/3-Ready Long-Acting Monoclonal Antibody (mAb) Designed for Seasonal Prevention of Lyme Disease (TNX-4800)

Exploring clinical development plan options including a controlled human infection model (CHIM) and a Phase 2/3 adaptive field study

Expect to have investigational product of TNX-4800 (anti-Borrelia OspA mAb) available for clinical trials in early 2027

Approximately 70 million people that live, work or vacation in areas of the U.S. in which Lyme Disease is endemic could potentially benefit from pre-exposure prophylaxis

CHATHAM, N.J., December 29, 2025 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully-integrated commercial stage biotechnology company, today announced program updates on TNX-4800 (formerly known as mAb 2217LS)[1,2], which is a long-acting human monoclonal antibody (mAb) that targets the outer surface protein A (OspA) of *Borrelia burgdorferi*, the causative agent of Lyme disease in humans. TNX-4800 is being developed for annual seasonal use, as one subcutaneous administration in the spring to protect against Lyme disease through fall, or the entire tick season in the U.S. There are no currently marketed U.S. Food and Drug Administration (FDA)-approved vaccines or prophylactics to protect against Lyme disease.

"We plan to meet with the FDA in 2026 to explore Phase 2/3 development options," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "We believe a controlled human infection model (CHIM)[3-5] study using *Borrelia*-infected ticks that mimics natural infection would be a potential path to demonstrating TNX-4800 efficacy for approval. We are on a path to have investigational product produced under Good Manufacturing Practices (GMP) available for testing early in 2027. We believe TNX-4800's long-acting mAb prophylaxis could play an important role for preventing Lyme for millions of people who live, work, and vacation in regions endemic for Lyme disease. TNX-4800 provides near-immediate immunity to the bacteria that cause Lyme disease after a single administration, which is very different from Lyme disease vaccine programs currently in development. Prophylaxis with TNX-4800 may also avoid the limitations of vaccine products designed to actively immunize against Lyme, including suboptimal immune responses from age, immunocompetence, and other reasons."

About TNX-4800

TNX-4800 (formerly known as mAb 2217LS) is a fully human monoclonal antibody with an engineered extended half-life that targets the outer-surface protein A (OspA) on Lyme-causing *Borrelia* bacteria. By binding OspA when TNX-4800 containing blood is ingested by the tick, TNX-4800 kills and blocks the maturation of *Borrelia burgdorferi* in the mid-gut of infected deer ticks. Published work in non-human primates showed that TNX-4800 was 95% effective in preventing infection after 6 days of exposure to ticks infected with Borrelia burgdorferi.[1] TNX-4800 was derived from mAb 2217 by amino acid substitutions in its crystallizable fragment (Fc) domain which served to prolong the serum half-life. A single administration in the Spring is designed to provide immunity within two days and maintain protective antibody titers for the entire tick season, providing pre-exposure prophylaxis against Lyme disease without relying on the recipient's immune system to generate antibodies. By delivering a well-characterized antibody directly, TNX-4800 has been shown to block transmission of the major *Borrelia* genospecies from ticks to animals. TNX-4800 also sidesteps the multidose schedules required for OspA vaccines in development[6] and FDA-approved vaccines that have been withdrawn from the market due to concerns about increased risk of autoimmunity.[7] Tonix intends to advance TNX-4800 through additional clinical trials with the goal of submitting a Biologics Licensing Application (BLA) to the FDA.

About TNX-4800 Pharmacokinetics

TNX-4800 was studied in a randomized, double-blind, sequential dose-escalation study (NCT04863287) that evaluated safety, tolerability, pharmacokinetics (PK), and immunogenicity of TNX-4800 in healthy adults. Forty-four subjects were randomized and 41 completed the study. Subjects received a single subcutaneous (SC) administration of placebo or TNX-4800 at 0.5, 1.5, 5, or 10 mg/kg. Safety was assessed via clinical and lab evaluations. Drug exposure increased by approximately 25-times for a 20-times increase in dose. Serum TNX-4800 was measurable at the earliest sampling time of 24 hours, indicating rapid systemic absorption. TNX-4800 concentrations remained quantifiable for >200 days in 80% of volunteers at the lowest dose and for up to 350 days in the majority of volunteers at higher doses (i.e., ≥ 1.5 mg/kg). Mean half-life ranged from 62–69 days across groups. Serum concentrations remained quantifiable for up to 12 months in most subjects. Mean exposure for the 10 mg/kg cohort was less than 20% of the highest exposures in a rat toxicology study. Anti-drug antibodies (ADA) were detected in <10% of treated subjects, with no impact on PK. Most adverse events were mild or moderate. TNX-4800 was determined to be generally safe and well tolerated.

About Lyme Disease

In the United States, Lyme disease is caused by the bacterium *Borrelia burgdorferi*. Lyme disease remains the most common vector-borne infection in the United States and its incidence is climbing each year.[8] It occurs most commonly in the Northeast, mid-Atlantic, and upper-Midwest regions. Lyme disease bacteria are transmitted through the bite of infected *Ixodes* ticks. Typical symptoms include fever, headache, fatigue, and a characteristic skin rash called erythema migrans. If left untreated, infection can spread to joints, the heart, and the nervous system. Laboratory testing is helpful if used correctly and performed with FDA-cleared tests. Although many cases of Lyme disease can be treated successfully with antibiotics, diagnosis and treatment are often delayed or missed, and even with treatment, up to 20% of cases may progress to a Post-Treatment Lyme Disease Syndrome (PTLDS) called "Chronic Lyme" or "Long Lyme". Chronic Lyme is considered an Infection Associated Chronic Illness (IACI), and is a chronic, debilitating disease state characterized by joint and muscle pain, fatigue and other symptoms.[9]

About *Borrelia Burgdorferi*

In infected deer ticks, *Borrelia's* OspA lipoprotein binds to tick-gut receptor TROSPA and helps it adhere to the midgut lining. During a tick bite blood meal, *Borrelia* downregulates OspA, upregulates OspC, and activates motility genes. *Borrelia* undergoes a metamorphic-like transformation, becoming highly flagellated and mobile, which facilitates migration to the tick salivary glands and invasion of human host tissues. During a tick bite of an animal pre-treated with TNX-4800, the tick ingests host blood containing TNX-4800, which kills and blocks the metamorphic-like transformation of *Borrelia* in the tick's midgut preventing transmission of the bacteria. Lyme-causing *Borrelia*-exposed or -infected individuals, rarely make antibodies against OspA which allows for people to be reinfected despite having immunity to OspC. Consequently, we expect that protection against *Borrelia* would require annual prophylaxis with TNX-4800.

About Monoclonal Antibody Prophylaxis

Two long-acting monoclonal antibody products[10,11] have won FDA approval for prophylaxis against respiratory syncytial virus (RSV). AstraZeneca (in partnership with Sanofi) markets Beyfortus™ (nirsevimab) and Merck markets Enflonsia™ (clesrovimab).

Tonix Pharmaceuticals Holding Corp.*

Tonix Pharmaceuticals is a fully-integrated biotechnology company with marketed products and a pipeline of development candidates. Tonix markets FDA-approved TONMYA™, a first-in-class, non-opioid analgesic medicine for the treatment of fibromyalgia, a chronic pain condition that affects millions of adults. TONMYA is the first new prescription medicine approved by the FDA for fibromyalgia in more than 15 years. TONMYA was investigated as TNX-102 SL. Tonix also markets two treatments for acute migraine in adults: Zembrace® SymTouch® (sumatriptan injection) and Tosymra® (sumatriptan nasal spray). Tonix's development portfolio* is focused on central nervous system (CNS) disorders, immunology, immuno-oncology, rare disease and infectious disease. TNX-102 SL is being developed to treat acute stress reaction and acute stress disorder under an Investigator-Initiated IND at the University of North Carolina in the OASIS study funded by the U.S. Department of Defense (DoD). TNX-102 SL is also in development for major depressive disorder. Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a Phase 2- ready Fc-modified humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. Tonix's rare disease portfolio includes TNX-2900, intranasal oxytocin potentiated with magnesium, in development for Prader-Willi syndrome and expected to start a potential pivotal Phase 2 study in 2026. Tonix's infectious disease portfolio includes TNX-801, a vaccine in development for mpox and smallpox, as well as TNX-4800, a Phase 2- ready long-acting humanized monoclonal antibody for the seasonal prevention of Lyme disease. Finally, TNX-4200 for which Tonix has a contract with the U.S. DoD's Defense Threat Reduction Agency (DTRA) for up to $34 million over five years, is a small molecule broad-spectrum antiviral agent targeting CD45 for the prevention or treatment of high lethality infections to improve the medical readiness of military personnel in biological threat environments. Tonix owns and operates a state-of-the art infectious disease research facility in Frederick, Md

* Tonix's product development candidates are investigational new drugs or biologics; their efficacy and safety have not been established and have not been approved for any indication.

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

Citations

[1]Schiller ZA, et al. *J Clin Invest.* 2021 131(11):e144843.

[2]Wang Y, et al.. *J Infect Dis*. 2016. 214(2):205-11.

[3]Cavaleri M, et al.. *Biologicals*. 2024. 85:101745.

[4]Abo YN, et al.. *Lancet Infect Dis*. 2023. 23(12):e533-e546.

[5]Ramanathan R, et al.. *Vaccine*. 2019 Jul 18;37(31):4256-4261.

[6]Comstedt P, et al. *Vaccine*. 2015 33(44):5982-8.

[7]Connaught's (ImuLyme™) and SmithKline Beecham's (LYMErix™) Lyme disease vaccines were withdrawn over concerns about an increased risk of autoimmune arthritis triggered by molecular mimicry, particularly in HLADRB1*0401 ("DR4+") individuals. Nigrovic LE, et al. *Epidemiol Infect.* 2007 135(1):1-8. doi: 10.1017/S0950268806007096. Epub 2006 Aug 8. PMID: 16893489; PMCID: PMC2870557.

[8]Gomes-Solecki M, et. al. *Clin Infect Dis.* 2020 70(8):1768-1773. doi: 10.1093/cid/ciz872. PMID: 31620776; PMCID: PMC7155782.

[9]National Academies of Sciences, Engineering, and Medicine. 2025. *Charting a Path Toward New Treatments for Lyme Infection-Associated Chronic Illnesses*. Washington, DC: The National Academies Press. https://doi.org/10.17226/28578.

[10]May 29, 2025. Sanofi Press Release. "Beyfortus public health advantage bolstered by first real-world comparison of infant vs maternal RSV immunization programs." https://bit.ly/40DeJGf

[11]June 9, 2025. Merck Press Release. "U.S. FDA Approves Merck's ENFLONSIA™ (clesrovimab-cfor) for Prevention of Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease in Infants Born During or Entering Their First RSV Season" https://bit.ly/4kkXDE8.

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 successfully launch and commercialize TONMYA and any of our approved products; risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; 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.

Indication and Usage

Zembrace® SymTouch® (sumatriptan succinate) injection (Zembrace) and Tosymra® (sumatriptan) nasal spray are prescription medicines used to treat acute migraine headaches with or without aura in adults who have been diagnosed with migraine.
Zembrace and Tosymra are not used to prevent migraines. It is not known if Zembrace or Tosymra are safe and effective in children under 18 years of age.

Important Safety Information

Zembrace and Tosymra can cause serious side effects, including heart attack and other heart problems, which may lead to death. Stop use and get emergency help if you have any signs of a heart attack:

- discomfort in the center of your chest that lasts for more than a few minutes or goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

Zembrace and Tosymra are not for people with risk factors for heart disease (high blood pressure or cholesterol, smoking, overweight, diabetes, family history of heart disease) unless a heart exam shows no problem.
Do not use Zembrace or Tosymra if you have:

- history of heart problems
- narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease)
- uncontrolled high blood pressure
- hemiplegic or basilar migraines. If you are not sure if you have these, ask your provider.
- had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation
- severe liver problems

- taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, or dihydroergotamine. Ask your provider for a list of these medicines if you are not sure.
- are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your provider for a list of these medicines if you are not sure.
- an allergy to sumatriptan or any of the components of Zembrace or Tosymra

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements.

Zembrace and Tosymra can cause dizziness, weakness, or drowsiness. If so, do not drive a car, use machinery, or do anything where you need to be alert.

Zembrace and Tosymra may cause serious side effects including:

- changes in color or sensation in your fingers and toes
- sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever
- cramping and pain in your legs or hips; feeling of heaviness or tightness in your leg muscles; burning or aching pain in your feet or toes while resting; numbness, tingling, or weakness in your legs; cold feeling or color changes in one or both legs or feet
- increased blood pressure including a sudden severe increase even if you have no history of high blood pressure
- medication overuse headaches from using migraine medicine for 10 or more days each month. If your headaches get worse, call your provider.
- serotonin syndrome, a rare but serious problem that can happen in people using Zembrace or Tosymra, especially when used with anti-depressant medicines called SSRIs or SNRIs. Call your provider right away if you have: mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; or trouble walking.
- hives (itchy bumps); swelling of your tongue, mouth, or throat
- seizures even in people who have never had seizures before

The most common side effects of Zembrace and Tosymra include: pain and redness at injection site (Zembrace only); tingling or numbness in your fingers or toes; dizziness; warm, hot, burning feeling to your face (flushing); discomfort or stiffness in your neck; feeling weak, drowsy, or tired; application site (nasal) reactions (Tosymra only) and throat irritation (Tosymra only).

Tell your provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of Zembrace and Tosymra. For more information, ask your provider.

This is the most important information to know about Zembrace and Tosymra but is not comprehensive. For more information, talk to your provider and read the Patient Information and Instructions for Use. You can also visit https://www.tonixpharma.com or call 1-888-869-7633.

You are encouraged to report adverse effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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