

TONIX
PHARMACEUTICALS

Corporate Presentation Abbreviated

July 2024

NASDAQ: TNXP

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Who We Are

Tonix is committed to developing and marketing therapeutics to treat pain, neurologic, psychiatric and addiction conditions through our *central nervous system portfolio* and within other areas of *high unmet need*, including immunology, infectious disease, and rare disease

With a Focus on:

Filing a New Drug Application (NDA) with the US Food and Drug Administration (FDA) for Tonmya™ (TNX-102 SL) for the management of Fibromyalgia (FM)

Key Clinical Programs

Molecule*	Indication	Phase 1	Phase 2	Phase 3	NDA Submission
Tonmya™ TNX-102 SL Cyclobenzaprine HCl Protectic® Sublingual Tablets	Fibromyalgia		Statistically Significant Phase 3 Topline Results Reported 4Q'23		Submission expected 2H'24
	Long COVID		Phase 2 Topline Results Reported 3Q'23		
	Acute Stress Disorder		Phase 2 Study** Start Expected 3Q'24		
TNX-1300 Cocaine Esterase NIDA Funded	Cocaine Intoxication		Phase 2 Study Start Expected 3Q'24		
TNX-2900 Intranasal Potentiated Oxytocin FDA Orphan Drug and Rare Pediatric Disease Designation	Prader-Willi Syndrome		Phase 2 Ready		
TNX-1500 Anti-CD40L mAb	Organ Transplant Rejection/ Autoimmune Conditions		Phase 1 Study Ongoing	Clinical Stage Completed	

*All of Tonix's product candidates are investigational new drugs or biologics and none has been approved for any indication.

**Investigator-initiated study

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Tonmya™

(TNX-102 SL, Cyclobenzaprine HCl Sublingual Tablets)

A unique, sublingual formulation of cyclobenzaprine designed to optimize delivery and absorption

Tonmya™ is conditionally accepted by the U.S. Food and Drug Administration (FDA) as the tradename for TNX-102 SL for the management of fibromyalgia. Tonmya has not been approved for any indication.

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About Fibromyalgia

Fibromyalgia is a **chronic pain disorder** resulting from amplified sensory and pain signaling within the CNS¹

Fibromyalgia is a **syndrome** comprised of the **symptoms**: chronic widespread pain, nonrestorative sleep, and fatigue



Multisite pain



Non-Restorative Sleep

Fatigue



Fibromyalgia is considered a **chronic overlapping pain condition (COPC)**
- the **only COPC with any FDA-approved drugs**³

Fibromyalgia is the prototypic nociplastic syndrome

¹American Chronic Pain Association (www.theacpa.org, 2019)

²CFS/ME = chronic fatigue syndrome/myalgic encephalomyelitis

³The three drugs with FDA approval for the treatment of fibromyalgia: Pregabalin (Lyrica®); Duloxetine (Cymbalta®); Milnacipran (Savella®)

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Fibromyalgia is a Large, Underserved and Dissatisfied Population

- **~10 million U.S. adults are affected – predominantly women^{1,2}**
 - Debilitating and life altering condition
 - Significant economic impact
- **Patients are dissatisfied, despite three FDA approved drugs^{3,4}**
 - 85% of patients fail first-line therapy⁵: efficacy variability, tolerability issues especially when used long-term and lack of broad-spectrum activity
 - Typical for patients to rotate between drugs and be on multiple drugs at the same time; 79% of FM patients are on multiple therapies⁵
- **~2.7 million FM patients diagnosed and treated⁶**
 - >22 million prescriptions are issued for the treatment of fibromyalgia (on- and off-label usage) each year^{7,8}
- **No new Rx product since 2009**
- *The treatment objective is to **restore functionality and quality of life** by broadly improving symptoms while avoiding significant side effects*

¹American College of Rheumatology (www.ACRPatientInfo.org accessed May 7, 2019) – prevalence rate of 2-4% for U.S. adult population (~250 million)

²Vincent A, et al. *Arthritis Care Res (Hoboken)*. 2013 65(5):786-92. doi: 10.1002; diagnosed prevalence rate was 1.1% of adult population or 50% of the prevalent population

³Robinson RL, et al. *Pain Med*. 2012 13(10):1366-76. doi: 10.1111; 85% received drug treatment

⁴The three drugs with FDA approval for the treatment of fibromyalgia: Pregabalin (Lyrica); Duloxetine (Cymbalta); Milnacipran (Savella)

⁵EVERSANA primary physician research, May 2024; commissioned by Tonix

⁶EVERSANA analysis of claims database, May 2024; commissioned by Tonix

⁷Product sales derived from IMS MIDAS; IMS NDTI used to factor usage for fibromyalgia; data accessed April 2015.

⁸Market research by Frost & Sullivan, commissioned by Tonix, 2011



Poor Sleep and Pain have Bi-directional Reinforcing Effects¹

- **Poor sleep and pain form a vicious cycle in driving fibromyalgia decompensation**
 - Can't sleep → worse pain / In pain → can't sleep
 - Poor sleep and pain contribute to persistence, chronicity and severity
 - Syndrome includes symptoms of fatigue and brain fog
- **Treating sleep disturbance in fibromyalgia has the potential to break the vicious cycle**
 - Potential to remove an obstacle to recovery
 - Using the right medicine is important – some sedative/hypnotics don't work^{1,2}



¹Moldofsky H, et al. *J Rheumatol*. 1996;23:529–533.

²Grönwald M, et al. *Clin Rheumatol*. 1993;12(2):186–191



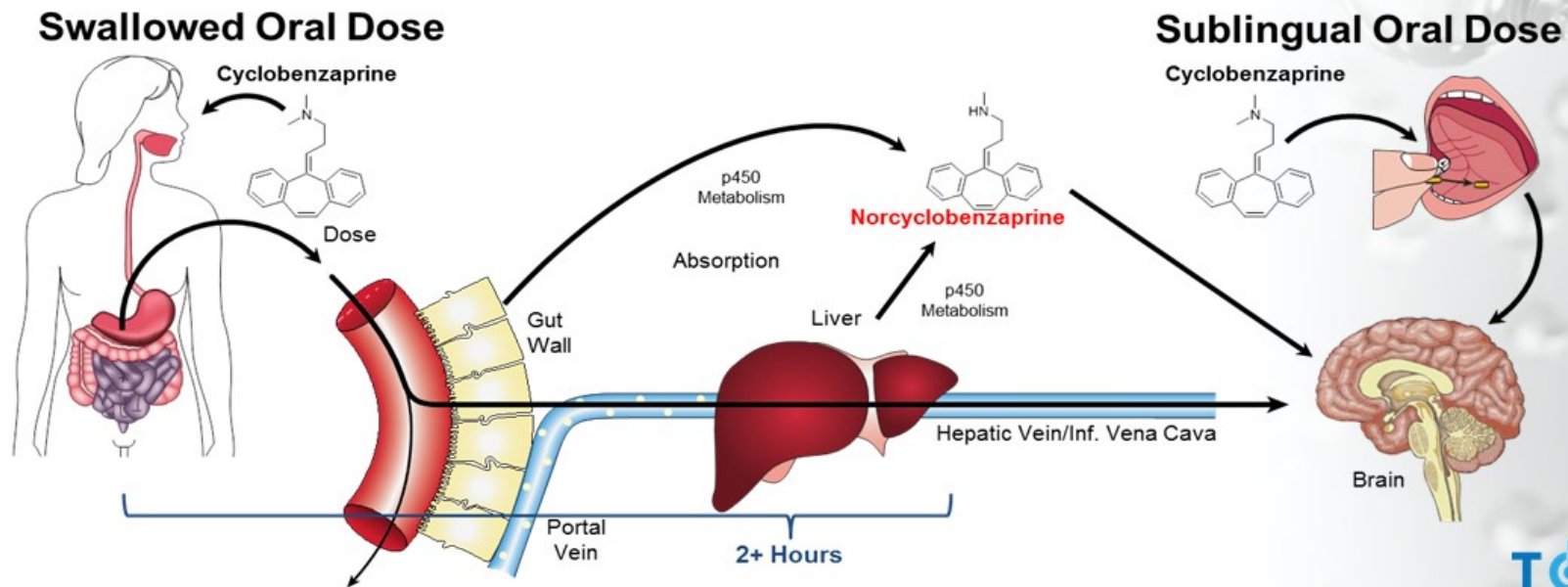
Tonmya™ (TNX-102 SL, Cyclobenzaprine HCl Sublingual Tablets)¹

- **Non-opioid analgesic designed for long-term daily bedtime use in fibromyalgia patients**
 - Targets non-restorative sleep
 - Potent binding and antagonist activities at four post-synaptic receptors
 - serotonin-5-HT_{2A}
 - α 1-adrenergic
 - histaminergic-H₁
 - muscarinic-M₁
 - No recognized risk for abuse
- **Improves sleep quality, does not increase sleep quantity:**
 - Not a traditional hypnotic or sedative
- **Proprietary, sublingual transmucosal formulation of cyclobenzaprine designed to optimize delivery and absorption**
 - Protectic® formulation based on eutectic composition of matter
 - Rapid absorption
 - Decrease in major metabolite by bypassing first-pass hepatic metabolism



TNX-102 SL: Sublingual Administration and Transmucosal Delivery

- Advantages of the sublingual route
- Faster absorption provides PK that is ideal for bedtime dosing
- Bypasses “first-pass” hepatic metabolism
- Reduced metabolism of parent CBP to active metabolite norcyclobenzaprine (nCBP)





Fibromyalgia Program Status

Tonmya™
(TNX-102 SL)

Cyclobenzaprine Protectic®
Sublingual Tablets

Fibromyalgia

**Statistically Significant 2nd Phase 3 Topline Results
Reported 4Q'23**

- **First pivotal Phase 3 study (*RELIEF*) reported – December 2020¹**
- **Second Phase 3 study (*RALLY*) missed primary endpoint – July 2021**
- **Confirmatory pivotal Phase 3 study (*RESILIENT*) reported – December 2023**
- **Type B CMC and clinical pre-NDA meetings with FDA completed with alignment on requirements for filing and potential approval**

Next Steps:

- **NDA filing expected 2H'24**
- **FDA decision on NDA approval expected 2H'25**

¹Lederman S, et al. *Arthritis Care Res (Hoboken)*. 2023 Nov;75(11):2359-2368. doi: 10.1002.

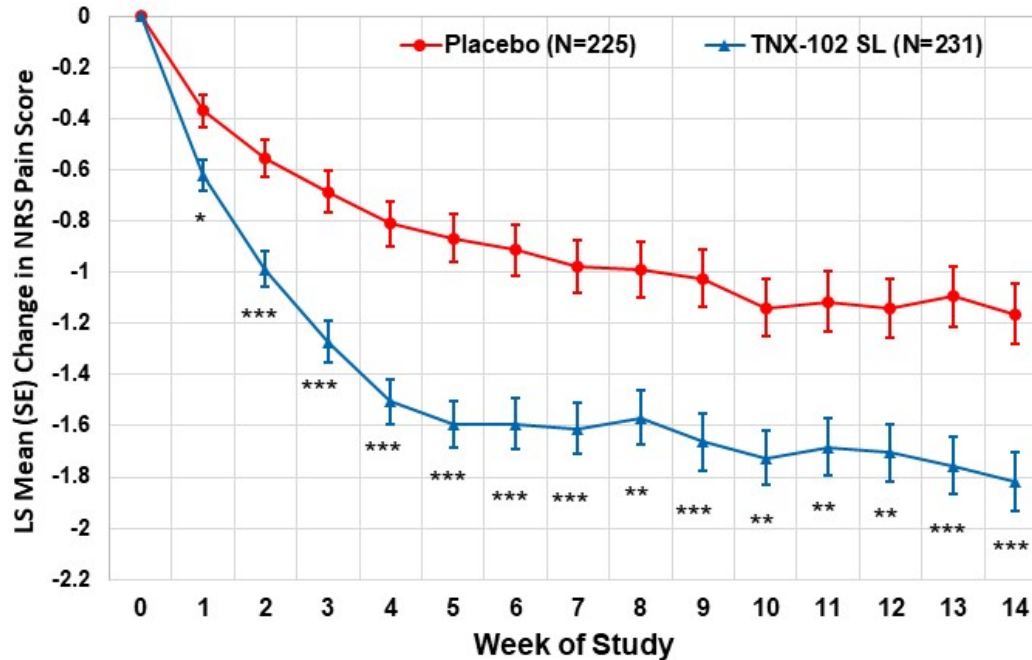
RESILIENT Primary Outcome Measure

Reduction in Widespread Pain



CNS PORTFOLIO

Weekly Average of Daily Diary NRS Ratings of Average Pain Over Prior 24 Hours



*p<0.01; **p<0.001; ***p<0.0001

Week 14 LS mean (SE) change from baseline for TNX-102 SL -1.82 (0.12) and for placebo -1.16 (0.12); LSMD from placebo -0.65 (0.16); **p=0.00005**[#]

[#]Based on Mixed Model Repeated Measures with Multiple Imputation, with fixed categorical effects of treatment, center, study week, and treatment by study week interaction, as well as baseline value and baseline value-by-study week interaction. Abbreviations: LS, least squares; LSMD, least squares mean difference; NRS, numerical rating scale; SE, standard error



RESILIENT Summary of Endpoints



CNS PORTFOLIO

Endpoint	P-value	Effect Size (ES)
Primary Endpoint		
Daily Diary Pain ratings	$p = 0.00005^{**}$	ES = 0.38
Key Secondary Endpoints*		
Patient Global Impression of Change (PGIC), responders	$p = 0.00013^{**}$	--
Fibromyalgia Impact Questionnaire – Symptoms domain	$p = 0.000002^{**}$	ES = 0.44
Fibromyalgia Impact Questionnaire – Function domain	$p = 0.001^{**}$	ES = 0.30
PROMIS Sleep Disturbance instrument	$p = 0.0000001^{**}$	ES = 0.50
PROMIS Fatigue instrument	$p = 0.00009^{**}$	ES = 0.37
Diary Sleep Quality ratings	$p = 0.0007^{**}$	ES = 0.32

*In order of statistical serial gate-keeping hierarchy (or, "waterfall") to control overall Type 1 error

**Statistical significance met

RESILIENT – Cognitive Dysfunction or “Brain Fog”



Brain Fog assessed by the FIQ-R¹ item on memory

- Patients rated their level of memory problems
- 11-pt scale going from “Good Memory” to “Very Poor Memory”
- Prespecified endpoint, but not in the “waterfall” with the key secondary endpoints
- TNX-102 SL patients vs PBO change from baseline LS mean (SE) difference of -0.8 (0.23)
- $p = 0.001$ (not corrected for multiple comparisons)
- Cohen’s d effect size = 0.31



Fatigue



¹FIQ-R = Fibromyalgia Impact Questionnaire - Revised



Tonmya™ Showed Broad-Spectrum Activity and was Well Tolerated

		Lyrica®	Cymbalta® Savella®	Tonmya™
Activity	Pain	YES	YES	YES
	Sleep	YES	-	YES
	Fatigue	-	YES	YES
Systemic Tolerability Issues	Insomnia	-	+	-
	Fatigue	+	-	-
	Weight	+	-	-
	Blood Pressure	-	+	-
	Sexual function	-	+	-
	GI issues	-	+	-

- Tonmya showed activity in all three measures of pain, sleep, and fatigue
- Tonmya is not associated with any of the commonly reported side effects of the FDA-approved medications for fibromyalgia

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Safety and Tolerability

- **Completion Rate (safety population): TNX-102 SL: 81.0% and Placebo: 79.2%**
- **No new safety signals observed**
- **Only systemic adverse events (AEs) at rate \geq 3.0% (TNX-102 SL v. Placebo)**
 - COVID-19 (4.3% v. 3.1%), somnolence (3.0% v. 1.3%), and headache (3.0% v. 1.8%)
- **As previously observed TNX-102 SL associated with administration site reactions**
 - Hypoaesthesia oral (23.8% v. 0.4%), product taste abnormal (11.7% v. 0.9%), paraesthesia oral (6.9% v. 0.9%), and tongue discomfort (6.9% v. 0%)
- **No effect on weight or blood pressure (BP)**
 - Weight: Week 14 change from baseline for TNX-102 SL of +0.04 lbs.; and for Placebo of +0.44 lbs.
 - Systolic BP: Week 14 change from baseline for TNX-102 SL of +0.7 mmHg; and for Placebo of +0.5 mmHg
 - Diastolic BP: Week 14 change from baseline for TNX-102 SL of +1.1 mmHg; and for Placebo of +0.2 mmHg
- **No sexual dysfunction AEs and improved female sexual functioning**
 - No reported AEs of any type of sexual dysfunction
 - Improvement in female sexual function using Changes in Sexual Functioning Questionnaire ($p=0.010$)



Treatment-Emergent Adverse Events (TEAEs) at Rate of $\geq 3\%$ in Either Treatment Group

System Organ Class Preferred Term	TNX-102 SL N=231	Placebo N=226	Total* N=457
Systemic Adverse Events			
COVID-19	10 (4.3%)	7 (3.1%)	17 (3.7%)
Somnolence	7 (3.0%)	3 (1.3%)	10 (2.2%)
Headache	7 (3.0%)	4 (1.8%)	11 (2.4%)
Oral Cavity Adverse Events			
Hypoaesthesia oral	55 (23.8%)	1 (0.4%)	56 (12.3%)
Product taste abnormal	27 (11.7%)	2 (0.9%)	29 (6.3%)
Paraesthesia oral	16 (6.9%)	2 (0.9%)	18 (3.9%)
Tongue discomfort	16 (6.9%)	0 (0.0%)	16 (3.5%)

*Safety Population

~50% of U.S. Fibromyalgia Patients are on Medicare: Prescription Coverage in Medicare Stands to Benefit from Changes in IRA



Approximately 50% of fibromyalgia patients are on Medicare

- EVERSANA analysis of claims database consisting of 2.2M patients, for which 1.2M claims were submitted throughout March 2002-March 2023¹

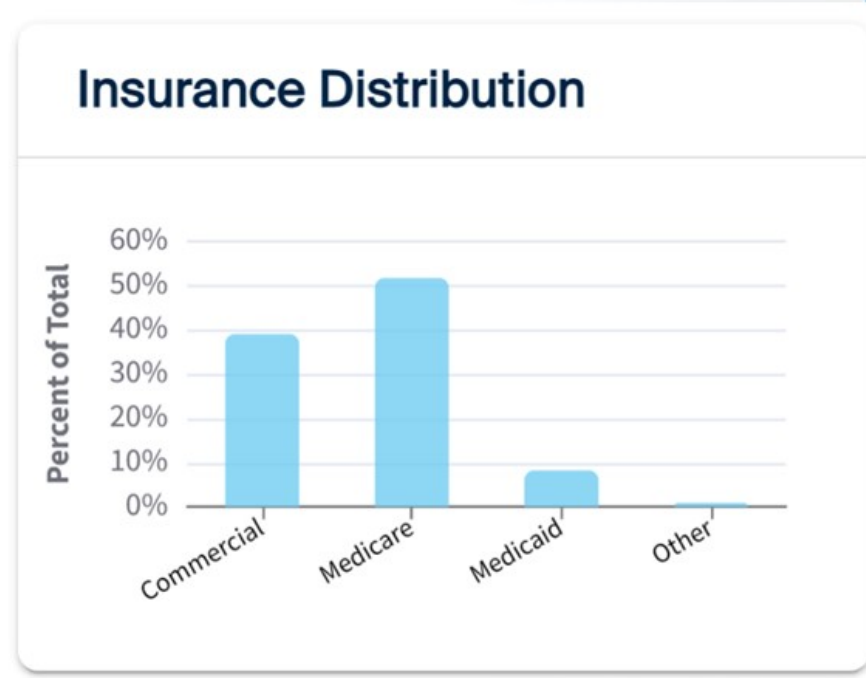
Beneficial Changes in 2025 to Medicare Part D through Inflation Reduction Act (IRA)²

- Medicare prescription payment plan to offer enrollees the option to pay out-of-pocket prescription drug costs in the form of capped monthly installment payments instead of all at once at the pharmacy
- Annual out-of-pocket costs will be capped at \$2,000 in year 2025
- Will replace the existing Coverage Gap Discount Program, which sunsets as of January 1, 2025

¹ EVERSANA analysis of claims database, May 2024; commissioned by Tonix

² Source: [Final CY 2025 Part D Redesign Program Instructions Fact Sheet | CMS](#)

Fibromyalgia Patients by Coverage¹



Prescribers Interviewed are Broadly Dissatisfied with Available Fibromyalgia Medications: Results of Primary Research¹



Perspectives on FM Therapies from Prescribers Interviewed		
Drug	Positives	Negatives
Duloxetine <i>(Cymbalta, generic)</i>	<ul style="list-style-type: none"> Relatively high efficacy (compared to alternatives) Can be titrated slowly from 20mg to 120mg 	<ul style="list-style-type: none"> Tolerability issues: worsening depression, insomnia Seldom used as a monotherapy; often requires adjunct
Pregabalin <i>(Lyrica, generic)</i>	<ul style="list-style-type: none"> Relatively high efficacy (compared to alternatives) Can often be safely combined with other medications 	<ul style="list-style-type: none"> Suboptimal for long-term use (e.g., weight gain) Schedule V status makes some HCPs more cautious to Rx
Savella <i>(milnacipran)</i>	<ul style="list-style-type: none"> Offers another option if patient fails Cymbalta or Lyrica 	<ul style="list-style-type: none"> Subpar efficacy does not counterbalance tolerability issues High cost and access constraints (~\$50/month)
Cyclobenzaprine <i>(Flexeril, generic; oral formulation, off-label)</i>	<ul style="list-style-type: none"> Active for initiating and sustaining sleep; can be titrated up Active for pain driven by stiffness and muscle spasms 	<ul style="list-style-type: none"> Mixed perspectives on pain benefit independent of sleep Suboptimal long-term results as efficacy wanes



85% of patients (avg) fail first line therapy



79% of FM patients (avg) are on multiple therapies

¹ EVERSANA primary physician research, May 2024; commissioned by Tonix

Opportunity for a New, Unique Fibromyalgia Treatment Option: Results of Primary Research from EVERSANA^{1,2}



FM Landscape

- Prescribers indicate a **very high unmet need** in FM (ranked ≥ 4.0 on a 5-point scale)
- Prescribers report there is **no standard of care in FM**, employ an **individualized approach** based on symptomology
- No new treatments approved since 2009
- Prescribers report minimal promotional activities by any pharmaceutical company
- Highly concentrated prescriber base with 50% of patients treated by ~16k physicians



Physician Primary Market Research

- **Physicians reacted positively to Tonmya's efficacy and safety profile (based on Phase 3 Study results)**
- Median interest = 4.0 on a 5-point scale
- Driving attributes included **strong efficacy, safety and tolerability**
- Unique & differentiating efficacy features included improvements in **sleep and fatigue**



Anticipated Use

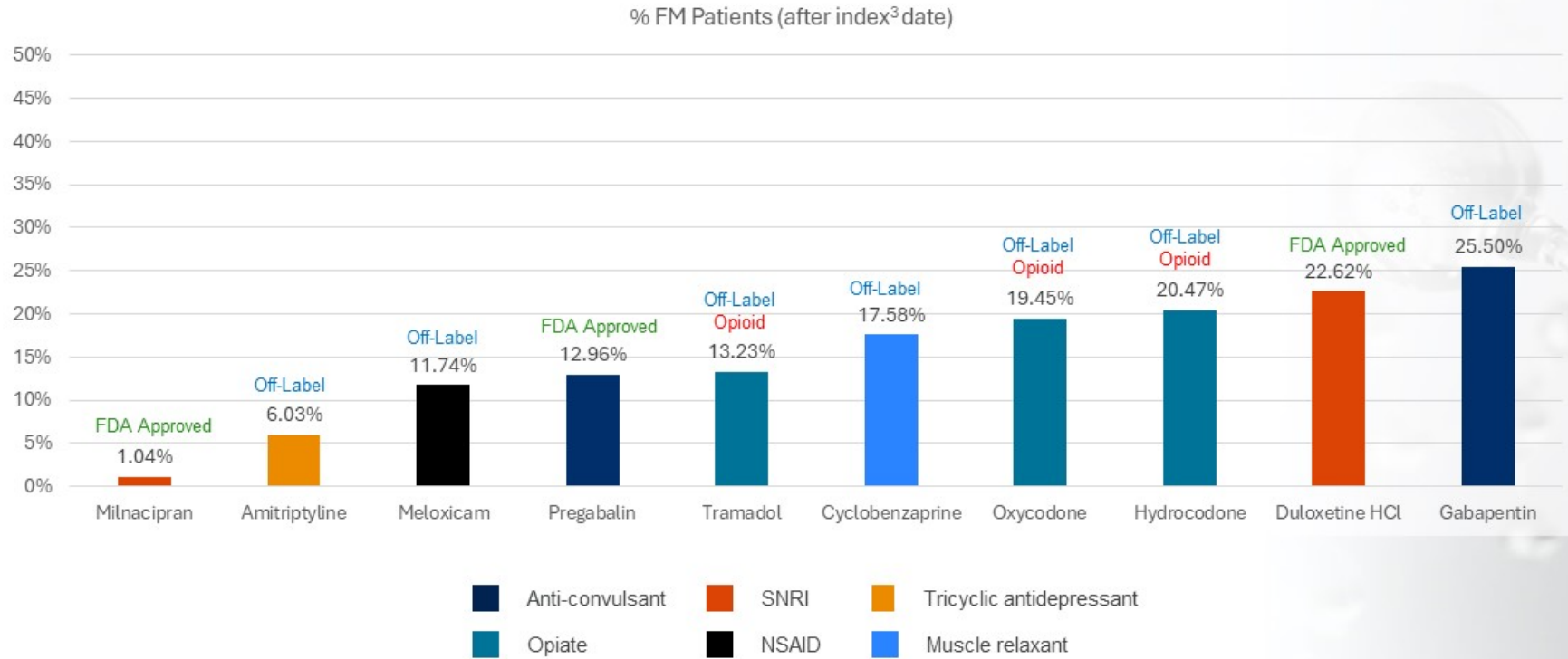
- **Physicians indicated intended use in 40% of their FM patients**
- Majority of respondents indicated Tonmya would be their first choice, if accessible
- Physicians surveyed indicated they are well-equipped to deal with access restrictions including prior authorizations and step-edits

¹ EVERSANA primary physician research, May 2024; commissioned by Tonix

² EVERSANA analysis of claims database, May 2024; commissioned by Tonix



Many Fibromyalgia Patients are Prescribed Off-Label Drugs; ~53% FM Patients Prescribed Opioids Off-Label^{1,2}



¹ 2022-2023

² EVERANA analysis of claims database, May 2024; commissioned by Tonix

³ Index date refers to date when ICD10 code was entered into database



Planning for Tonmya™ Launch and Marketing

Several companies that successfully developed CNS drugs have launched them

- Big Pharma wants the commercial launch de-risked before acquisition (e.g., Nurtec®)

Company		Mkt Cap ¹	Product	Indication	FDA Approval	Exit
Axsome	AXSM	\$3.5 B	Auvelity®	Depression	8/2022	
Biohaven	BHVN	\$3.0 B	Nurtec®	Migraine	2/2020	Sold to PFE for \$12 B in Oct 2022
IntraCellular	ITCI	\$7.2 B	Caplyta®	Schizophrenia	12/2019	
Supernus	SUPN	\$1.4 B	Oxtella-XR®	Seizures	1/2019	
Neurocrine	NBIX	\$13.6 B	Ingrezza®	Tardive Dyskinesia	4/2017	
Acadia	ACAD	\$2.5 B	Nuplazid®	Parkinson's psychosis	4/2016	

To prepare for the launch of Tonmya, Tonix acquired two marketed Rx drugs: Zembrace® and Tosymra®

- Both are indicated for the acute treatment of migraine

¹Accessed June 7, 2024



Two Marketed Proprietary Migraine Drugs Non-oral Formulations of Sumatriptan

Zembrace® SymTouch® (sumatriptan injection) 3 mg¹



Tosymra® (sumatriptan nasal spray) 10 mg²



- Each indicated for the *treatment of acute migraine with or without aura in adults*
- Sumatriptan remains the acute migraine ‘gold standard’ treatment for many patients and continues to represent the largest segment of the market in terms of unit sales³
- Each may provide migraine *pain relief in as few as 10 minutes* for some patients^{1,2,4,5}
- Patents to 2036 (Zembrace) and 2031 (Tosymra)

Acquired from Upsher-Smith Laboratories which has managed care contracts covering ~200 M lives

- Contract includes a transition period during which Tonix expects to secure its own contracts

Tonix Medicines Commercial Subsidiary

- Complete commercialization capability
 - Manage supply chain and contract manufacturer
 - Distribution
 - Trade, Managed Care & Government contracting
- Team of professionals including Sales & Marketing personnel

¹Zembrace SymTouch [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC: February 2021 - For more information, talk to your provider and read the [Patient Information](#) and [Instructions for Use](#). – Important Safety Information is provided in the appendix

²Tosymra [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC: Feb 2021.

For more information, talk to your provider and read the [Patient Information](#) and [Instructions for Use](#). – Important Safety Information is provided in the appendix

³Tonix Medicines, Inc.; Data On File, 2023

⁴Mathew NT, et al. Dose ranging efficacy and safety of subcutaneous sumatriptan in the acute treatment of migraine. US Sumatriptan Research Group. Arch Neurol. 1992;49(12):1271-1276.

⁵Wendt J, et al. A randomized, double-blind, placebo-controlled trial of the efficacy and tolerability of a 4-mg dose of subcutaneous sumatriptan for the treatment of acute migraine attacks in adults. Clinical Therapeutics. 2006;28(4):517-526.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines, Inc. Intravail is a registered trademark of Aegis Therapeutics, LLC, a wholly owned subsidiary of Neurelis, Inc.

CNS-Focused Biopharma with Preclinical, Clinical and Commercial Stage Products



Tonmya™ for Fibromyalgia: Preparing New Drug Application (NDA)

- Two Phase 3 trials completed with statistical significance on primary endpoint
- Pre-NDA meetings with FDA completed with alignment on requirements for filing and potential approval
- NDA filing expected 2H'24
- FDA decision on NDA approval expected 2H'25



Marketed Products

- Zembrace® and Tosymra® indicated for the treatment of acute migraine



Pipeline

- Phase 2 biologic cocaine antidote, FDA “Breakthrough Therapy Designation”
- Phase 1 anti-CD40L monoclonal antibody to prevent organ transplant rejection



Strategic Partnerships

- With government institutions, world-class academic & research organizations



Internal Capabilities

- Commercial prescription drug sales
- R&D and clinical-trial scale manufacturing

*Tonmya™ is conditionally accepted by the U.S. Food and Drug Administration (FDA) as the tradename for TNX-102 SL for the management of fibromyalgia

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Additional Potential Indications for Tonmya™ (TNX-102 SL)

Fibromyalgia-Type Long COVID

- Status: Phase 2
- Phase 2 study (*PREVAIL*) completed
- Topline results reported 3Q 2023

Next Steps: Meet with FDA

Acute Stress Reaction/ Acute Stress Disorder

- Phase 2 ready investigator-initiated study
- Department of Defense funded
- UNC will perform study
- Received IND clearance from FDA

Next Steps: Expect to start Phase 2 in 3Q 2024



Additional Programs and Pipeline Strategy

Focusing on government and academic collaborations

- Validates Tonix's scientific expertise and technology
- Reduces internal spend
- Increases number of trials
- Potentially speeds time to market
- Grants, contracts, cost-sharing or "in-kind" arrangements

TNX-1500: Next Generation anti-CD40L mAb

Re-engineered to better modulate the binding of Fc γ R and mitigate risk of thrombosis

Clinical Stage of Phase 1 study completed

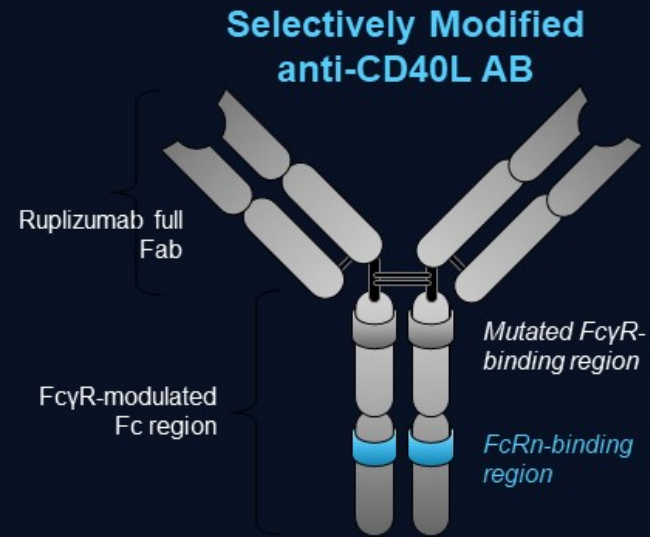
Key Differentiators

Expected to deliver efficacy without compromising safety

First Generation: Development halted due to thromboembolic (TE) complications—blood clots—traced to Fc gamma receptor (Fc γ R)

Second Generation: Eliminated the Fc γ R TE complication but potency and half life was reduced, limiting utility

Third Generation (TNX-1500): Re-engineered to better modulate the binding of Fc γ R.



Contains the full ruplizumab Fab and the engineered Fc region that modulates Fc γ R-binding, while preserving FcRn function

*TNX-1500 has not been approved for any indication.

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External Partnerships

Government partners providing direct funding, cost sharing or in-kind support include:

- ***National Institutes of Health (NIH)***
- ***National Institute of Allergy and Infectious Disease (NIAID)***
 - TNX-1800 selected for Project NextGen
- National Institute on Drug Abuse (NIDA)
 - TNX-1300 for cocaine intoxication; Phase 2 study funding
- ***Department of Defense (DoD)***
 - TNX-4200 for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments
 - TNX-102 SL for ASD; investigator-initiated Phase 2 study funding

Academic partners sponsoring clinical trials of Tonix's investigational drug products include:

- Massachusetts General Hospital (MGH)
- University of Washington
- University of North Carolina

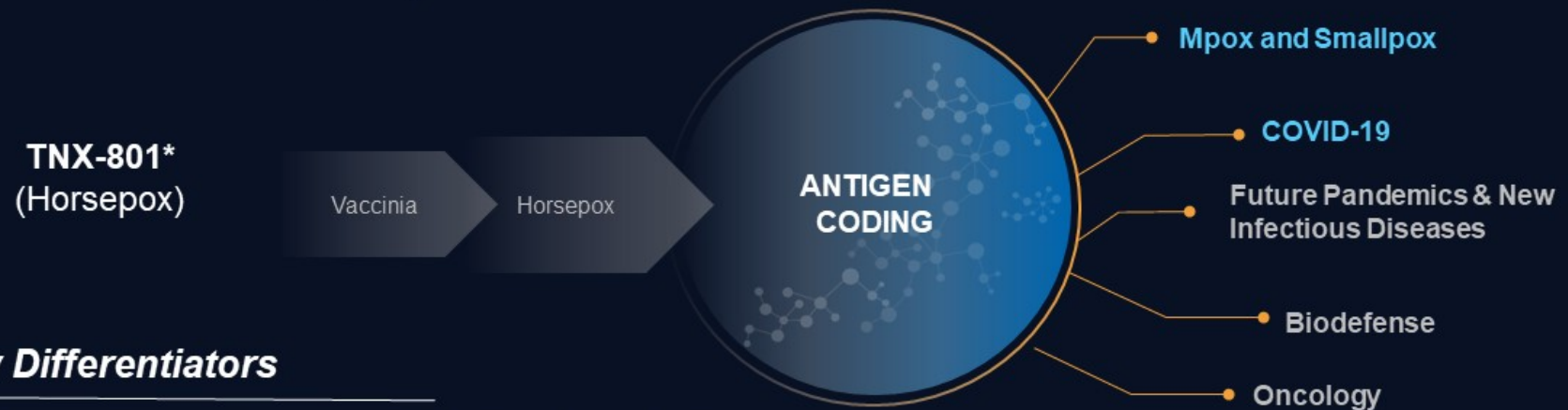
TNX-801

Live Virus Vaccine

Live virus vaccine platform with multitude of potential applications

TNX-801: Recombinant Pox Vaccine (RPV) Platform Using Live Virus Technology

Cloned version of horsepox¹ purified from cell culture



Key Differentiators

Live virus vaccines are the most established vaccine technology

- Prevents forward transmission
- Effective in eliciting durable or long-term immunity

Economical to manufacture at scale

- Low dose because replication amplifies dose *in vivo*
- Single administration

Standard refrigeration for shipping and storage

*TNX-801 is in the pre-IND stage of development and has not been approved for any indication.
¹Noyce et al., 2018. *PLoS One*. 13(1):e0188453.



TNX-1800: Designed to Express the SARs-CoV-2 Spike Protein

TNX-1800 (recombinant horsepox virus) is a live virus vaccine based on Tonix's TNX-801 that is designed to express the spike protein of the SARS-CoV-2 virus and to elicit a predominant T cell response

- Immunogenic and well tolerated¹
- Showed promise in protecting animals from challenge with SARS-CoV-2 delivered directly into the lungs¹

Status: *National Institute of Allergy and Infectious Diseases (NIAID) will conduct a Phase 1 clinical trial with TNX-1800*

- First vaccine candidate using Tonix's live virus recombinant pox virus (RPV) platform technology to enter clinical trials
- "Project NextGen" is an initiative by the U.S. Department of Health and Human Services (HHS) to advance a pipeline of new, innovative vaccines and therapeutics for COVID-19. NIAID will be conducting clinical trials to evaluate several early-stage vaccine candidates, including TNX-1800
- Phase 1 study is designed to assess safety and immunogenicity in approximately 60 healthy adult volunteers
- Upon completion of the trial, NIAID and Tonix will assess the results and determine the next steps for the development of TNX-1800

¹Awasthi, M. et al. *Viruses*. 2023. 15(10):2131.

²Awasthi, M. et al. *Vaccines (Basel)*. 2023. 11(11):1682.



Broad-Spectrum Antiviral Discovery Programs

Host-directed antiviral discovery programs

- **TNX-4200: CD45 targeted therapeutics**
 - Small molecule therapeutics that reduce endogenous levels of CD45, a protein tyrosine phosphatase
 - Reduction in CD45 protects against many viruses including the Ebola virus
- **Cathepsin inhibitors**
 - Small molecule therapeutics that inhibit **essential cathepsins** which are required by viruses such as coronaviruses and filoviruses to infect cells
 - Activity as monotherapy and in combination with other antivirals

Virus-directed antivirals discovery program

- **Viral glycan-targeted engineered biologics**
 - Bind to viral densely branched high-mannose (DBH) glycans
 - **Neutralize circulating virus** and stop the entry of the progeny virus into cells
 - Antiviral activity against a broad range of RNA viruses
 - Activity as monotherapy and in combination with other antivirals

R&D Center (RDC): Frederick, MD

- Accelerated development of vaccines and antiviral drugs against infectious diseases
- ~48,000 square feet, BSL-2 with some areas designated BSL-3

Key Partnerships

TNX-1500: ALLOGRAFT REJECTION



MASSACHUSETTS
GENERAL HOSPITAL



HARVARD
MEDICAL SCHOOL

TNX-102 SL: ACUTE STRESS DISORDER



U.S. Department of Defense



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

TNX-2900: PRADER-WILLI SYNDROME



Inserm Transfert
Your partner in health innovation



TNX-1300: COCAINE INTOXICATION



National Institute
on Drug Abuse



COLUMBIA
UNIVERSITY

TNX-1800: COVID-19 VACCINE



National Institutes
of Health



National Institute of
Allergy and
Infectious Diseases

TNX-4200: BROAD-SPECTRUM ANTIVIRAL



U.S. Department of Defense



TONIX
PHARMACEUTICALS



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**TEAM,
NETWORK, &
UPCOMING
MILESTONES**

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Management Team



Seth Lederman, MD
Co-Founder, CEO & Chairman



Gregory Sullivan, MD
Chief Medical Officer



Bradley Saenger, CPA
Chief Financial Officer



Jessica Morris
Chief Operating Officer



Milestones: Recently Completed and Upcoming

Tonmya™ Milestones

- 4th Quarter 2023 Statistically significant topline results of Phase 3 RESILIENT study for Tonmya™ for the management of fibromyalgia
- 2nd Quarter 2024 Type B CMC and clinical pre-NDA meetings with FDA for Tonmya™ for fibromyalgia
- 2nd Half 2024 Submit NDA to FDA for Tonmya™ for fibromyalgia

Other Key Program Milestones

- 3rd Quarter 2024 Initiate Phase 2 study of TNX-102 SL for acute stress disorder
- 3rd Quarter 2024 Initiate Phase 2 study of TNX-1300 for the treatment of cocaine intoxication

THANK YOU

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Zembrace® Important Safety Information (1 of 2)

Zembrace Sym Touch (Zembrace) 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 is 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 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, dihydroergotamine; 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

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

Zembrace 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® Important Safety Information (2 of 2)

Zembrace 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, 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 include: pain and redness at injection site; 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.

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. For more information, ask your provider.

This is the most important information to know about Zembrace but is not comprehensive. For more information, talk to your provider and read the [Patient Information](#) and [Instructions for Use](#). You can also visit www.upsher-smith.com or call 1-888-650-3789. For full Prescribing Information, visit: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6e5b104f-2b9e-416e-92fb-ef1bd8aea867d>

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

Zembrace is a prescription medicine used to treat acute migraine headaches with or without aura in adults who have been diagnosed with migraine.

Zembrace is not used to prevent migraines. It is not known if it is safe and effective in children under 18 years of age.



Tosymra® Important Safety Information (1 of 2)

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

Tosymra is 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 is done and shows no problem.

Do not use 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; severe liver problems; hemiplegic or basilar migraines. If you are not sure if you have these, ask your healthcare provider.
- Had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation; taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, or dihydroergotamine. Ask your provider if you are not sure if your medicine is listed above
- 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 ingredient in Tosymra

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



Tosymra® Important Safety Information (2 of 2)

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 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.
- Seizures even in people who have never had seizures before

The most common side effects of Tosymra include: tingling, dizziness, feeling warm or hot, burning feeling, feeling of heaviness, feeling of pressure, flushing, feeling of tightness, numbness, application site (nasal) reactions, abnormal taste, and throat irritation.

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 Tosymra. For more information, ask your provider.

This is the most important information to know about 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 www.upsher-smith.com or call 1-888-650-3789. For full Prescribing Information, visit: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=015a5cf9-f246-48bc-b91e-cd730a53d8aa>

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

Tosymra is a prescription medicine used to treat acute migraine headaches with or without aura in adults.

Tosymra is not used to treat other types of headaches such as hemiplegic or basilar migraines or cluster headaches.

Tosymra is not used to prevent migraines. It is not known if Tosymra is safe and effective in children under 18 years of age.

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