

Health Alert:

Tianeptine Update - Continued Cases Despite January 2024 Recall



Image courtesy of New Jersey Poison Information and Education System (NJPIES)

September 2024 Update

Despite a January 2024 nationwide recall on tianeptine products from Neptune Resources, LLC, NJ DOH has continued to receive reports of tianeptine involved poisonings and has identified tianeptine-involved overdose deaths in the past year. Tianeptine is a substance with opioid-like effects that has been falsely marketed and sold across the state in gas stations, online as a dietary supplement, and has caused various life-threatening health consequences in users.

More specifically, since January 2024, the New Jersey's Poison Control Center (NJPIES) has received 17 reports of poisoning cases associated with the tianeptine products. The last and most recent poisoning case reported to NJPIES on August 3, 2024. Through the NJ State Unintentional Drug Overdose Reporting System (SUDORS), NJDOH has also identified six tianeptine-involved overdose deaths since June of 2023, with the most recent tianeptine-involved death occurring in March of 2024. In addition to tianeptine, toxicology reports of overdose decedents also identified the following substances involved with the deaths: buprenorphine, mitragynine, trazadone, clonazepam, venlafaxine, Benadryl, Delta-9-tetrahydrocannabinol (THC), and alcohol. Among these overdose deaths, victims ranged from 32 to 48 years of age, and deaths occurred in Bergen, Ocean, Monmouth, and Mercer counties. The NJDOH will continue to monitor for tianeptine related poisonings and/or deaths and provide updated health alerts as applicable.

Health Department Action Requested

At this time, The New Jersey Department of Health's Public Health and Food Protection Program (PHFPP) is requesting the assistance of all local health departments (LHDs) to investigate fuel station convenience stores and any other retail food establishments where the

recalled Neptune Fix products may be located. If found, the products should be voluntarily destroyed or embargoed, if refusals are encountered.

PHFPP also requests that LHDs report the types and quantities of products, locations, and actions (destroyed or embargoed) to phfpp@doh.nj.gov.

January 2024 Recall

On January 28, 2024, the company Neptune Resources, LLC announced a voluntary, nationwide recall on all lots of Neptune's Fix Elixir, Neptune's Fix Extra Strength Elixir and Neptune's Fix tablet products, in which all contain tianeptine, an active ingredient not U.S. Food and Drug Administration (FDA) approved for any use. On January 29, 2024, the FDA issued a risk statement advising that those who consume Neptune Resources, LLC tianeptine products are at risk for life-threating health consequences including, but not limited to, suicidal ideation or behavior for children, adolescents and young adults ages 25 and younger.

Further, the FDA warns that the use of tianeptine can lead to unintentional overdose with other life-threatening risks including, confusion, seizures, drowsiness, dry mouth, and shortness of breath, which also may be exacerbated when used with alcohol and antidepressants such as monoamine oxidase inhibitors (MAOIs). Neptune Resources, LLC notified distributors of the recall through a mailed letter which requested all recalled products to be returned to the company. Any consumers, distributors or retailers who possess the any of the products being recalled should stop use of such products, destroy and/or return the products to where its place of purchase immediately.

To read more about the recall of Neptune Resources, LLC products, visit the link below.

 $\underline{https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/neptune-resources-llc-\underline{issues-voluntary-nationwide-recall-neptunes-fix}$

What is Tianeptine?

Tianeptine is a tricyclic antidepressant used in some Latin American, Asian, and European countries but is not FDA approved or regulated for use in the United States. Individuals with an opioid use disorder may be more likely to use tianeptine, as it is inaccurately marketed as a safer alternative to opioids and can have opioid-like effects. The FDA has warned that manufacturers of tianeptine are making inaccurate and unproven claims that use of tianeptine can improve brain function, treat anxiety, depression, pain, opioid use disorder, and other health ailments.

Health and Safety Risks

According to the FDA, U.S. poison control centers have seen an increase in reports of adverse reactions to tianeptine exposure over the past two decades. Tianeptine can cause opioid-like effects, as it binds to and acts as an agonist at the mu opioid receptors. Repeated use of tianeptine can cause dependence and withdrawal symptoms when use is stopped. Symptoms of tianeptine withdrawal are similar to those of opioid withdrawal, including agitation, nausea, anxiety, diarrhea, and chills. Some <u>cases of withdrawal</u> have been severe, with patients requiring intubation. Common symptoms associated with tianeptine exposure include:

- Agitation
- Drowsiness
- Confusion
- Sweating
- Rapid heartbeat
- Increased blood pressure
- Nausea and vomiting
- Slow or stopped breathing
- Coma
- Death

A <u>CDC study</u> on tianeptine exposures found that outcome severity was associated with concomitant exposure to other substances, including benzodiazepines, alcohol, and opioids.

Recommendations for Providers

- Providers who suspect tianeptine exposure in any patient should call New Jersey's Poison Center (NJPIES) at 1-800-222-1222. Experts are standing by 24 hours a day, 7 days a week to help in the diagnosis, treatment, and prevention of poisoning. This line is also available to the general public.
- Treatment for suspected tianeptine exposure should involve vital sign monitoring, symptomatic supportive care, and an ECG evaluation. NJPIES, if contacted regarding a suspected exposure, will provide additional patient-focused management.
- Counsel patients regarding the risks of tianeptine. Remind patients that just because a substance is conveniently sold does not mean it is safe.
- Provide person-centered and trauma-informed care to patients, even if they are not ready to stop using.
- Carry naloxone and encourage its use when a person's respiration is depressed, or if an opioid overdose is suspected. Though limited, there is some <u>evidence</u> that naloxone may have efficacy in treating tianeptine toxicity.
- Educate patients on overdose risk-prevention strategies, such as avoiding mixing substances.
- Refer individuals to local harm reduction agencies or other trusted, community-based providers available to connect patients to needed resources (i.e., sterile syringes, overdose education, HIV testing, fentanyl test strips, etc.).
- Share information or provide a warm handoff to ReachNJ.
- For more information, please contact Amanda Gan at the New Jersey Department of Health at Amanda.Gan@doh.nj.gov.
- For media inquiries regarding tianeptine, visit the link below and complete the digital press intake form at Department of Health | News (nj.gov)