Voluntary Recall of Neptune Resources Products

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-threatening 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 any of the products being recalled should stop use of such products, destroy and/or return the products to its place of purchase immediately.

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


Background

In August 2023, the New Jersey Poison Center (NJPIES) identified a cluster of poisoning cases involving tianeptine, a substance with opioid-like effects that is being falsely marketed and sold across the state in gas stations and online as a dietary supplement. Common names for tianeptine include “gas station heroin,” “ZaZa Red,” or “Neptune’s Elixir” (among others). Tianeptine use can lead to serious health complications and even death.

Over the 60-day period from June 17 to August 17, NJPIES received 9 calls about patients poisoned by tianeptine, and some patients have become critically ill. Due to this cluster of cases and previous FDA warnings, the New Jersey Department of Health (NJDOH) has increased surveillance efforts around this substance and urges New Jersey residents to be cautious.

In October 2023, NJDOH was made aware of another cluster of 10 additional Tianeptine exposures in New Jersey involving the substance. More specifically, these poisonings were
attributed to products sold under the names of “Neptune’s Fix”, “Neptune’s Fix Elixir” and “Pegasus Silver.” More than half of the patients impacted suffered from central nervous system (CNS) depression and seizures after ingestion, with some requiring hospitalization and intubation. Others presented to the hospital with slurred speech, altered mental status, agitation, chest discomfort, tachycardia, tremors, hallucinations, urinary retention, vomiting, and lethargy. Patients were treated in hospitals in Hudson, Atlantic, Middlesex, Monmouth, Ocean, Salem, Gloucester, Burlington, Mercer, and Passaic counties. An analysis conducted by NJPIES identified the presence of tetrahydrocannabinol (THC), cannabidiol (CBD), and synthetic cannabinoids in samples of these products, in addition to tianeptine.

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

**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 cases of withdrawal 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 CDC study 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 evidence 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 [https://www.nj.gov/health/news/home/contact.shtml](https://www.nj.gov/health/news/home/contact.shtml).