

AND FAMILY SERVICES KENTUCKY ALL SCHEDULE ELECTRONIC REPORTING (KASPER) SYSTEM

Important Notice: Tianeptine Becomes a Schedule I Controlled Substance in Kentucky

Effective March 23, 2023, all tianeptine products became Schedule 1 controlled substances in Kentucky. All applicable provisions of KRS Chapter 218A and 902 KAR Chapter 55 apply.

What is tianeptine?

Tianeptine, which is available online and in convenience stores and gas stations, has no known medical use. It has been linked to serious harm, overdoses and death according to the U.S. Food and Drug Administration (FDA). The drug is approved for use in other parts of the world, where it is marketed as Coaxil or Stablon. Coaxil and Stablon are not approved by the Food and Drug Administration for medical use in the United States. Tianeptine, also known as tianeptine sulfate, tianeptine sodium powder, tianaa, tianna green, tianna red, tianna white, Pegasus or Za Za. Tianeptine is commonly sold as an adulterated dietary supplement or sold as not for human consumption. The cabinet took action to include tianeptine in the list of scheduled or controlled substances in response to increasing awareness and concerns regarding potential misuse. **As a Schedule I controlled substance, tianeptine products can no longer be sold.**

What is a Schedule I controlled substance?

The Drug Enforcement Administration regulates medications as controlled substances. Their placement is determined by their accepted medical use, potential for abuse and safety or dependence liability. States are permitted to add a drug to their state's controlled substances. Schedule 1 controlled substances are those drugs with:

- The drug or other substance has a high potential for abuse.
- The drug or other substance has no currently accepted medical use in treatment in the United States.
- There is a lack of accepted safety for use of the drug or other substance under medical supervision.

Examples of other Schedule 1 drugs include heroin, lysergic acide diethylamide (LSD) and methaqualone.

Why were Tianeptine products schedule as a Schedule 1 controlled substance?

Side effects from abusing or misusing Tianeptine by itself or with other drugs, like antidepressants or anti-anxiety medications, include agitation, drowsiness, confusion, sweating, rapid heartbeat, high blood pressure, nausea, vomiting, slowed or stopped breathing, coma and death. Reports of bad reactions and unwanted effects are increasing. Cases described in medical journals, calls to poison control centers and reports to the FDA suggest tianeptine has a potential for abuse. People with a history of opioid-use disorder or dependence may be at particular risk of abusing tianeptine, according to the FDA.

How does this impact prescribers and pharmacists?

Since Tianeptine has not been available for prescribing and dispensing, there will be no impact on those practices. Prescribers and pharmacists may want to learn more on the impact of Tianeptine use. Below you will find some articles:

- Centers for Disease Control, Morbidity and Mortality Weekly Report: <u>Characteristics of Tianeptine Exposures</u> <u>Reported to the National Poison Data System</u> — United States, 2000–2017 (8/3/2018)
- US Food and Drug Administration: <u>Tianeptine Products Linked to Serious Harm, Overdose, Death</u> (02/10/2022)
- US Food and Drug Administration: <u>Tianeptine in Dietary Supplements</u>(02/22/2023)