Drug Enforcement Administration
Diversion Control Division
Drug & Chemical Evaluation Section

Xylazine

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(Trade Names: Rompun®, AnaSed®; Street Names: Tranq)

Introduction:

Xylazine is a substance that is in approved drugs used in veterinary medicine as a sedative with analgesic and muscle relaxant properties. Xylazine was first synthesized in 1962 by Bayer Pharmaceutics and was investigated for potential human use in clinical trials as an analgesic, sleeping aid, and anesthetic. However, these trials were terminated due to its severe hypotension and central nervous system (CNS) depressant effects.

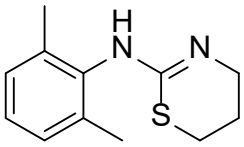
There has been an increase in the number of reports, alerts, and advisories from media and public health agencies indicating that xylazine is being abused in combination with other drugs of abuse, such as fentanyl, and is causing harm.

Licit Uses:

The U.S. Food and Drug Administration (FDA) has approved specific products containing xylazine for veterinary use only. Approved drugs for veterinary use are available as a 20 mg/ml and 100 mg/ml injectable solution. Typically, the approved drugs are administered in animals either alone or in conjunction with other anesthetics (e.g., ketamine or barbiturates) intravenously or intramuscularly.

Chemistry:

The chemical structure of xylazine is shown below.



Xylazine is structurally similar to the class of compounds known as phenothiazines. The molecular formula is $C_{12}H_{16}N_2S$ with a molecular weight of 220.34 g/mol. The Chemical Abstract Service (CAS) number is 7361-61-7. The IUPAC name is *N*-(2,6-dimethylphenyl)-5,6-dihydro-4*H*-1,3- thiazin-2-amine and it commonly exists as the hydrochloride salt form. Analytical techniques such as gas chromatography (GC) and liquid chromatography (LC) paired with mass spectrometry (MS) and nitrogen phosphorous detector (NPD) are the common means of detection in biological specimens. Immunoassay is not commonly used for detection in biological specimens.

Pharmacology:

Xylazine is an alpha-2 adrenergic receptor agonist. In published animal studies, xylazine decreased the release of norepinephrine and dopamine in the CNS.

According to the FDA-approved product label for veterinary use, xylazine has an onset of action within 10 to 15 minutes after intramuscular injection in animals. A sleeplike state, the depth of which is dose-dependent, is usually maintained for 1 to 2 hours, while analgesia lasts from 15 to 30 minutes. The centrally-acting muscle relaxant effect causes relaxation of the skeletal musculature, complementing sedation and analgesia.

User Population:

Although xylazine is not approved for human use, the National Institute of Drug Abuse (NIDA) notes exposure to xylazine is common amongst heroin, fentanyl, and cocaine abusers.

Toxicity:

According to NIDA, published human case reports note xylazine is a CNS depressant that can cause drowsiness amnesia, and slow breathing, heart rate, and blood pressure to dangerously low levels. Other toxic effects reported include blurred vision, disorientation, staggering, coma, miosis, and hyperglycemia. Severe skin lesions (necrotic tissue) have been observed in individuals taking fentanyl contaminated with xylazine. Exposure to xylazine has required medical intervention to treat various symptoms.

NIDA also reports taking opioids in combination with xylazine and other CNS depressants such as alcohol or benzodiazepines, increases the risk of life-threatening overdose. However, because xylazine is not an opioid, naloxone (an opioid antagonist) does not address the impact of xylazine on breathing.

Fatalities involving xylazine have also been reported. However, most overdose deaths linked to xylazine involved additional substances such as: fentanyl, heroin, benzodiazepines, alcohol, gabapentin, methadone, prescription opioids, and cocaine.

Illicit Uses and Distribution:

Xylazine is often used in combination with illicit substances, knowingly or unknowingly, but may also be abused alone. Additionally, published case reports have demonstrated that xylazine has been used in drug-facilitated crimes to induce sleep.

Advisories and alerts regarding the dangers of xylazine use have been issued by multiple public health departments and poison control centers.

According to DEA's National Forensic Laboratory Information System (NFLIS) Drug database, which collects scientifically verified data on drug items and cases submitted to and analyzed by participating federal, state, and local forensic laboratories in the United States, xylazine was identified in 149 items in 2015, 345 in 2016, 442 in 2017, 665 in 2018, 1,682 in 2019, 3,449 in 2020, 9,146 in 2021, and 10,361 in 2022. These data represent a significant increase in law enforcement seizures of xylazine nationwide.

Control Status:

Xylazine is not controlled under the Controlled Substances Act, however, there may be state-specific controls.

FDA regulates articles containing xylazine when they meet the definition of a drug under the Federal Food, Drug, and Cosmetic Act. On February 28, 2023, FDA issued an import alert regarding the unlawful importation of xylazine.

Comments and additional information are welcomed by the Drug and Chemical Evaluation Section, Telephone 571-362-3249, or E-mail DPE@dea.gov.