Drug Enforcement Administration
Diversion Control Division
Drug & Chemical Evaluation Section

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XYLAZINE

(Trade Names: Rompun®, Sedazine®, AnaSed®)

Introduction:

Xylazine is a drug used in veterinary medicine as a sedative with analgesic and muscle relaxant properties. It is used on many different animal species—such as cattle, sheep, horses, dogs, cats, deer, rats, and elk—to calm and facilitate handling, perform diagnostic and surgical procedures, relieve pain, or act as a local anesthetic.

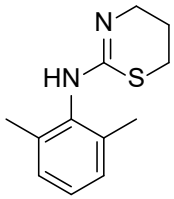
Reports, alerts, and advisories indicate an increased xylazine prevalence as an adulterant in drugs of abuse mixtures. This non-narcotic agent was first synthesized in 1962 by the Bayer Company. Xylazine has been studied in humans for its potential use as an analgesic, hypnotic, and anesthetic, but these clinical trials were terminated due to xylazine's severe hypotension and central nervous system depressant effects.

Licit Uses:

Xylazine is approved by the Food and Drug Administration (FDA) for veterinary use only. Xylazine is available in liquid solutions at 20, 100, and 300 mg/mL. Typically, this drug is administered either alone or in conjunction with other anesthetics (e.g., ketamine or barbiturates) intravenously, intramuscularly, or orally for sedative and relaxant properties.

Chemistry:

Xylazine is chemically known as *N*-(2,6-dimethylphenyl)-5,6-dihydro-4*H*-1,3-thiazin-2-amine. It has a molecular formula of $C_{12}H_{16}N_2S$ and a molecular weight of 220.34 g/mol. The Chemical Abstract Service (CAS) number is 7361-61-7, and xylazine commonly exists as the hydrochloride salt form. Common analytical techniques to detect xylazine in biological specimens includes gas chromatography and liquid chromatography paired with mass spectrometry and nitrogen-phosphorous detector. The chemical structure of xylazine is shown below:



Pharmacology:

The pharmacology of xylazine is well established in animal species; however, human studies are scarce. Xylazine acts as an agonist at alpha-2 adrenergic receptors and decreases the release of norepinephrine and dopamine in the central nervous system. This results in effects such as analgesia, sedation, and muscle relaxation. Also, xylazine may have cholinergic, serotonergic, dopaminergic, alpha-1 adrenergic, histaminergic, or opiate receptor mechanisms.

Xylazine typically has an onset of effects within a few minutes and lasts up to 4 hours in animals. Pharmacokinetics between animal species did not vary significantly. The major biotransformed metabolite is 2,6-dimethylaniline. Phase I metabolism includes dealkylation, oxidization, and hydroxylation. Phenolic metabolites were excreted in the glucuronide or sulfate forms. Hydroxylated metabolites were detected in human urine with overdose cases.

Reported concentrations of xylazine in humans vary. Non-fatal cases documented toxic effects, including blurred vision, disorientation, drowsiness, staggering, coma, bradycardia, respiratory depression, hypotension, miosis, and hyperglycemia. Unfortunately, therapeutic, toxic, and lethal concentrations in humans cannot be established due to the overlap of fatal and nonfatal concentrations reported. Higher concentration exposures required medical intervention to treat various symptoms.

Illicit Uses:

Xylazine is often used as an adulterant with illicit substances.

User Population:

Exposure to xylazine is common amongst heroin, fentanyl, and cocaine abusers due to its use as an adulterant. Exposure cases include both intentional and accidental dosing.

Illicit Distribution:

Xylazine is not approved for human use. Reports have demonstrated that, other than its use as an adulterant, xylazine was used in drug-facilitated crimes to induce sleep.

The Drug Enforcement Administration's National Forensic Laboratory Information System (NFLIS) Drug database collects scientifically verified data on drug items and cases submitted to and analyzed by participating federal, state, and local forensic drug laboratories. NFLIS-Drug received over 76,000 reports of xylazine, with 149 reports in 2015; 3,475 in 2020; 9,330 in 2021; 12,095 in 2022; 23,152 in 2023; and 23,998 in 2024 (reports still pending).

Many public health departments and poison control centers issued advisories and alerts. Seizure activity has also been reported nationwide, with large quantities found in Pennsylvania, Connecticut, and California.

Control Status:

Xylazine is not controlled under the Controlled Substances Act. However, import shipments of xylazine bulk drug, xylazine active pharmaceutical ingredient, or finished drug products containing xylazine may be detained under the Federal Food, Drug, and Cosmetic Act (FD&C), if it does not have labeling that bears adequate directions for use unless it is exempted. Shipments of drug products containing xylazine that are, or appear to be, adulterated or misbranded may also be detained under the FD&C.

Comments and additional information are welcomed by the Drug and Chemical Evaluation Section; Fax 571-362-4250, Telephone 571-362-3249, or Email DPE@dea.gov.