Warning About Xylazine, a Veterinary Sedative Found in Illicit Drugs

Patients who don’t respond to naloxone may have overdosed on an opioid containing xylazine, a sedative and pain reliever approved for animals, not humans, the FDA recently cautioned.

Xylazine can cause serious and life-threatening adverse effects that resemble those associated with opioid use, the agency warned in a letter to clinicians. The letter said the FDA is aware that xylazine, which is not an opioid, is increasingly being detected in the illicit drug supply, most commonly in combination with heroin and fentanyl, and in drug overdoses. Xylazine has also been combined with stimulants such as methamphetamine and cocaine. Users of the illicit drugs may not be aware of xylazine’s presence in their supply, the letter noted.

Among the harms associated with acute and repeated xylazine exposure are delayed diagnosis and management of a polycystic kidney disease; severe, necrotic skin ulcerations; and interference with the treatment of opioid use disorder. The letter recommends health care professionals consider xylazine exposure if patients develop skin ulcerations or withdrawal symptoms that can’t be managed with traditional opioid use disorder treatments. There are no FDA-approved medications to manage xylazine withdrawal in symptomatic people, and the drug is not detected in routine toxicology screenings.

In a statement, the agency said it is continuing to investigate whether the xylazine found in heroin and other illicit drugs is diverted from the animal supply or produced illegally for human use.

Health care professionals and patients should report adverse events resulting from possible xylazine exposure to their local health department, poison center, and the FDA’s MedWatch Adverse Event Reporting program, the agency advised in the letter.

Some Naloxone Products Could Be Sold Without a Prescription

Certain naloxone products, which reverse opioid overdoses, could be safe and effectively developed such a label, an attempt to help manufacturers switch naloxone products from prescription to over-the-counter products.

Making naloxone products available without a prescription would help expand access to them, preventing overdose deaths, FDA Commissioner Robert Califf, MD, said in a statement. The agency is seeking comments from the public on the proposed switch, which must be received by January 17, 2023.

Illegal e-Cigarettes Targeting Youth

Five companies recently received FDA warning letters for selling illegal e-cigarettes designed to look like toys, food, and cartoon characters.

“The designs of these products are an utterly flagrant attempt to target kids,” Brian King, PhD, MPH, director of the agency’s Center for Tobacco Products, said in a statement. The e-cigarettes look like glow sticks and popsicles and other items popular with youth and feature characters from video games, television shows, and films, such as The Simpsons, Squid Game, and Minions.

None of the products’ manufacturers had submitted a premarket application to the FDA, whose approval is necessary before a new tobacco product is introduced to the market. The agency said it has issued more than 440 warning letters to companies marketing illegal e-cigarettes containing tobacco-derived nicotine.

The FDA considers e-cigarettes without marketing authorization to be adulterated and misbranded. If the companies marketing them fail to correct violations, the FDA can seek a permanent injunction, seizure, or civil money penalties.

Analyzing 2022 National Youth Tobacco Survey data, the FDA and the US Centers for Disease Control and Prevention found that 14.1% of high school students reported having used e-cigarettes in the previous 30 days and more than one-quarter of those who vaped said they did so every day. – Rita Rubin, MA

Note: Source references are available through embedded hyperlinks in the article text online.