FDA adds abuse warning to labels for Xanax, Valium

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(HealthDay)—Reacting to an upsurge in abuse of benzodiazepine

sedatives such as Valium, Xanax and Ativan, U.S. officials on Wednesday added a "Boxed Warning" to the drugs' labels, cautioning about the danger.

Benzodiazepines are tranquilizers commonly prescribed to help ease issues such as anxiety, seizures, insomnia and panic disorders.

But "while benzodiazepines are important therapies for many Americans, they are also commonly abused and misused, often together with opioid pain relievers and other medicines, alcohol and illicit drugs," U.S. Food and Drug Agency Commissioner Dr. Stephen Hahn said in an agency news release.

So he said the FDA is now "taking measures and requiring new labeling information to help health care professionals and patients better understand that while benzodiazepines have many treatment benefits, they also carry with them an increased risk of abuse, misuse, addiction and dependence."

Illicit use of "benzos" has been on the rise, and the drugs are often taken along with opioid drugs—sometimes to deadly effect.

In fact, in a report released last year by the U.S Centers for Disease Control and Prevention, benzos were found to be involved in a full third of all fatal opioid overdoses. The drugs were also involved in nearly two-thirds of overdoses tied to the lethal synthetic opioid fentanyl. The report looked at 2017-2018 data from 25 states.

According to the FDA, in 2019 alone, more than 92 million prescriptions were written for benzodiazepines, with the most commonly used drugs in this class being alprazolam/Xanax (38%), followed by clonazepam/Klonopin (24%), and then lorazepam/Ativan (20%).

"Benzodiazepines are very helpful for short term treatment" of disorders for which they are recommended, said Dr. Teresa Murray Amato, chair of emergency medicine at Long Island Jewish Forest Hills, in New York City.

However, the key phrase is "short term": Benzos are typically recommended for use for less than a month. Amato noted that, according to recent FDA data, "approximately 50% of benzodiazepine prescriptions were for over two months of medications."

So, "providers need to consider the risks and benefits of prescribing longer courses of these medications," she said. "The FDA is hoping that by adding verbiage to the current warning, providers will be extra careful in not only prescribing these medications, but also to be mindful of the duration," according to Amato.

Addiction to benzodiazepines doesn't take long to grab hold, the FDA noted.

"Physical dependence can occur when benzodiazepines are taken steadily for several days to weeks," the agency said, and "patients who have been taking a benzodiazepine for weeks or months can have withdrawal signs and symptoms when the medicine is discontinued abruptly."

Weaning yourself off the tranquilizers requires guidance from a physician, the agency stressed.

"Stopping benzodiazepines abruptly or reducing the dosage too quickly can result in acute withdrawal reactions, including seizures, which can be life-threatening," the FDA said.

Amato agreed.

"If you are currently taking benzodiazepines and have concerns, please speak to your doctor," she said. "Do not stop taking them if you have been on them for a prolonged period of time before speaking with your health care provider.

For patients that are on these medications, there needs to be close medical supervision to safely taper dosages."

In addition to adding the new Boxed Warning, medication guides that accompany the drugs will be revised to better inform patients of the danger of abuse, the agency said.

More information: The U.S. National Institute on Drug Abuse has more about benzodiazepines.