



September 23, 2020

## New Boxed Warning for Benzodiazepines

The FDA has issued a Drug Safety Communication (DSC) to alert clinicians about updated Boxed Warnings for all benzodiazepines to address the serious risk of abuse, addiction, physical dependence, and withdrawal reactions. These warnings will be included in prescribing information and Medication Guides to help educate patients and caregivers about these risks.

Benzodiazepines are commonly prescribed medicines. In 2019, an estimated 92 million benzodiazepine prescriptions were dispensed from U.S. outpatient retail and mail-order pharmacies, with alprazolam (38%) being the most common followed by clonazepam (24%) and lorazepam (20%).

Post-marketing data suggest that benzodiazepine abuse and misuse are common and that associated harms are substantial but occur primarily when people use benzodiazepines in combination with other drugs. The exact risk of addiction associated with benzodiazepine use is uncertain; however, population data clearly indicate that both primary benzodiazepine use disorders and polysubstance addiction involving benzodiazepines do occur.

### Recommendations for Health Care Professionals:

- Assess risks for abuse, misuse, and addiction prior to prescribing or continuing benzodiazepine therapy.
- Assess other treatments that could increase risks of adverse drug events (particularly opioids or other medications that may depress the CNS).
- Consider all therapeutic options for management of the patient's condition, and provide information about non-drug alternatives.
- Warn patients and caregivers about the risks of abuse, misuse, addiction, dependence, and withdrawal and the associated signs and symptoms.
- Warn patients and caregivers about the serious risks of taking benzodiazepines with alcohol or other substances, including opioids.
- Use a patient-specific plan to gradually taper benzodiazepine dosage when discontinuing.
- Abrupt discontinuation can result in life-threatening withdrawal reactions:

Catatonia	Homicidal thoughts	Suicidal ideation
Seizures	Mania	Hallucinations
Delirium tremens	Psychosis	Depression

The complete Drug Safety Communication can be viewed on the [FDA website](#).

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To help the FDA track safety issues with medicines, please report adverse events involving benzodiazepines or other medicines to the MedWatch program as recommended in the [Indian Health Manual](#). Instructions for reporting can be found online at the [NPTC Pharmacovigilance website](#).