

September 28, 2020

COM-2020-072

DRUG SAFETY NOTIFICATION



DATE: September 23, 2020

**DRUG NAME: Benzodiazepine
Drug Class**

**DRUG INDICATION:
Generalized anxiety disorder,
insomnia, seizures, social
phobia, and panic disorder**

**SAFETY TOPIC: Boxed Warning
Updated to Improve Safe Use**

Dear provider of pharmaceutical services,

PharmPix is committed to our member's health and wellness. The clinical team wants to communicate you with the latest up-to-date information on drug safety. For this reason, we notify you that the U.S. Food and Drug Administration (FDA) is requiring the Boxed Warning for all the benzodiazepines to be updated to include additional information about the risks of abuse, misuse, addiction, physical dependence, and withdrawal reactions. Updates are also being required to several sections of the [prescribing information](#) and the existing [Medications Guides](#) of all the benzodiazepines.

Recommendations for healthcare professionals:

- Consider the patient's condition and the other drugs being taken, and assess the risk of abuse, misuse, and addiction.
- Limit each medicine dosage and duration to the minimum needed to achieve the desired clinical effect when prescribing benzodiazepines, alone or in combination with other drugs.
- Use a gradual taper to reduce the dosage or to discontinue benzodiazepines to reduce the risk of acute withdrawal reactions.
- Take precautions when using benzodiazepines in combination with opioid addiction medications.
- Report adverse events or side effects at [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#) by any of the following ways:
 - Complete and submit the [MedWatch Online Voluntary Reporting Form](#) online.
 - [Download](#) FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Additional information can be found at [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#) and [FDA's Drug Safety and Availability portal](#).

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: <https://www.pharmpix.com/providers/>.

Regards,

PharmPix Clinical Department

Reference(s):

- Benzodiazepine Drug Class: Drug Safety Communication. U.S. Food and Drug Administration. (2020). Retrieved 24 September 2020, from <https://www.fda.gov/safety/medical-product-safety-information/benzodiazepine-drug-class-drug-safety-communication-boxed-warning-updated-improve-safe-use>.
- FDA expands Boxed Warning to improve safe use of benzodiazepine drug. U.S. Food and Drug Administration. (2020). Retrieved 24 September 2020, from <https://www.fda.gov/drugs/drug-safety-and-availability/fda-requiring-boxed-warning-updated-improve-safe-use-benzodiazepine-drug-class>.