



Opioid Addiction Medications in Patients Taking Benzodiazepines or CNS Depressants: Drug Safety Communication - Careful Medication Management Can Reduce Risks

September 20, 2017

Audience: Health Professional, Pain Management

ISSUE: Based on additional review, FDA is advising that the opioid addiction medications **buprenorphine** and **methadone** should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS). The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care professionals can reduce these risks. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment (MAT) drugs and benzodiazepines together.

BACKGROUND: Many patients with opioid dependence may also use benzodiazepines or other CNS depressants, either under a health care professional's direction or illicitly. Although there are serious risks with combining these medicines, excluding patients from MAT or discharging patients from treatment because of use of benzodiazepines or CNS depressants is not likely to stop them from using these drugs together. Instead, the combined use may continue outside the treatment setting, which could result in more severe outcomes.

RECOMMENDATIONS: Health care professionals should take several actions and precautions and develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. These include:

- Educating patients about the serious risks of combined use, including overdose and death, that can occur with CNS depressants even when used as prescribed, as well as when used illicitly.
- Developing strategies to manage the use of prescribed or illicit benzodiazepines or other CNS depressants when starting MAT.
- Tapering the benzodiazepine or CNS depressant to discontinuation if possible.
- Verifying the diagnosis if a patient is receiving prescribed benzodiazepines or other CNS depressants for anxiety or insomnia, and considering other treatment options for these conditions.
- Recognizing that patients may require MAT medications indefinitely and their use should continue for as long as patients are benefiting and their use contributes to the intended treatment goals.
- Coordinating care to ensure other prescribers are aware of the patient's buprenorphine or methadone treatment.
- Monitoring for illicit drug use, including urine or blood screening.

Patients taking MAT drugs should continue to take these medicines as prescribed. Do not stop taking other prescribed medicines without first talking to your health care professional. Before starting any new medicines, tell your health care professional that you are taking MAT. Do not take non-prescribed benzodiazepines or other sedatives (See Table 2 in the Drug Safety Communication, List of Benzodiazepines and Other CNS Depressants) or use alcohol when taking MAT because the combined use increases the possibility of harm, including overdose and death.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- **Download form** 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

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