

Important Drug Safety Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC23-031-CG
May 26, 2023

FDA announced that, is requiring updates to the Boxed Warning and other information to ensure the prescribing information is made consistent across the entire class of these medicines. The current prescribing information for some prescription stimulants does not provide up to date warnings about the harms of misuse and abuse, and particularly that most individuals who misuse prescription stimulants get their drugs from other family members or peers. Further, individuals who are prescribed stimulants are often faced with requests to share their medication. Sharing these medicines with others can lead to development of substance use disorder and addiction in those with whom these drugs are shared.

RECOMMENDATIONS

Health Care Professionals

- Assess patient risk of misuse, abuse, and addiction before prescribing stimulant medicines.
- Counsel patients not to share their prescribed stimulant with anyone else.
- Educate patients and their families on these serious risks, proper storage of the medicine, and proper disposal of any unused medicine.
- Throughout treatment, regularly assess and monitor them for signs and symptoms of nonmedical use, addiction, and potential diversion, which may be evidenced by more frequent renewal requests than warranted by the prescribed dosage.

Patients and Caregivers

- Always take your prescription stimulant exactly as prescribed by your health care professional.
- Do not take more of the medicine or take it more often than prescribed.
- Never provide any of your prescription stimulant medicine to anyone else as it can have serious risks for those for whom it was not prescribed.
- Store your prescription stimulant medicines securely, out of sight and reach of children and in a location not accessible by others, including visitors to the home.
- Immediately dispose of unused or expired prescription stimulants properly or take them to a drug take-back site, location, or program.

- Talk to your health care professional if your use of prescription stimulants has resulted in problems with your health, relationships, responsibilities, or the law, or if you are struggling with misusing these or other medicines.
- Go to an emergency room or call 911 if you experience symptoms of stimulant overdose, including new tremors or change in existing tremors, seizures, restless or aggressive behavior, overactive reflexes, fast breathing, fast or irregular pulse rate, confusion, stomach cramps, or more serious symptoms such as heart attack or stroke.

Pharmacy

- Talk to your health care professional if you have questions or concerns about risks of taking prescription stimulants. Expect patients to visit your pharmacy asking for information on this safety issue and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

FDA Updating Warnings to Improve Safe Use of Prescription Stimulants Used to Treat ADHD and Other Conditions

[Posted 05/26/2023]

AUDIENCE: Patient, Health Professional, Pharmacy, Psychiatry, Pediatrics

ISSUE: The FDA is requiring updates to the *Boxed Warning* and other information to ensure the prescribing information is made consistent across the entire class of these medicines. The current prescribing information for some prescription stimulants does not provide up to date warnings about the harms of misuse and abuse, and particularly that most individuals who misuse prescription stimulants get their drugs from other family members or peers. Further, individuals who are prescribed stimulants are often faced with requests to share their medication. Sharing these medicines with others can lead to development of substance use disorder and addiction in those with whom these drugs are shared.

Prescription stimulants can be an important treatment option for disorders for which they are indicated. However, even when prescribed to treat an indicated disorder, their use can lead to misuse or abuse. Misuse and abuse, also called nonmedical use, can include taking your own medicine differently than prescribed or using someone else's medicine. For this reason, sharing prescription stimulants with those for whom they are not prescribed is an important concern and a major contributor to nonmedical use and addiction. Misuse and abuse of prescription stimulants can result in overdose and death, and this risk is increased with higher doses or unapproved methods of taking the medicine such as snorting or injecting.

BACKGROUND: Prescription stimulants are used to treat attention deficit/hyperactivity disorder (ADHD), binge-eating disorder, and uncontrollable episodes of deep sleep called narcolepsy. Prescription stimulants may help decrease impulsivity and hyperactivity and increase attention in patients with ADHD; help reduce the number of excessive overeating episodes in patients with binge-eating disorder; and help promote wakefulness in patients with narcolepsy. These medicines have benefits when used appropriately, but they also have serious risks, including the risk of misuse and abuse, addiction, overdose, and death. Examples of common prescription stimulants include Adderall (amphetamine/dextroamphetamine), Concerta (methylphenidate), Dexedrine (dextroamphetamine), and Ritalin (methylphenidate).

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- Talk to your health care professional if you have questions or concerns about risks of taking prescription stimulants.

Health care 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.accessdata.fda.gov/scripts/medwatch

- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form, or submit by fax to 1-800-FDA-0178.