COMMUNICATION

COM-2023-028

22
MAY
2023

URGENT
PLEASE
REVIEW

Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug safety information.

U.S. Food & Drug Administration Publication Date:

05/11/2023

Drug Indication:

Attention deficit hyperactivity disorder (ADHD), binge-eating disorder, narcolepsy

Safety Topic:

FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions

Stimulants and Updates to Warnings

It is for this reason that we are notifying you that on 05/12/2023 the U.S. Food and Drug Administration (FDA) published a safety communication for the following product(s): stimulants.

Reason for Communication:

To address continuing concerns of misuse, abuse, addiction, and overdose of prescription stimulants, the FDA is requiring updates to the *Boxed Warning, Warning and Precautions, Drug Abuse and Dependence, Overdosage*, and *Patient Counseling* sections to ensure the prescribing information is made consistent across the entire class of stimulants. The FDA is requiring adding information that patients should never share their prescription stimulants with anyone. The *Boxed Warning* information will describe the risks of misuse, abuse, addiction, and overdose consistently across all medicines in the class. It will also advise healthcare professionals to monitor patients closely for signs and symptoms of misuse, abuse, and addiction.

Pharmacy Required Action:

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.

Remember you can report adverse events related to this or any other drug product 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.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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REFERENCES:
1. U.S. Food and Drug Administration. (2023). FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions. https://www.fda.gov/drugs/drug-safety-and-availability/fda-updating-warnings-improve-safe-use-prescription-stimulants-used-treat-adhd-and-other-conditions
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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