COMMUNICATION

COM-2025-040

1 JULY 2025

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 you with the latest up-to-date drug safety information.

U.S. Food & Drug Administration Publication Date:

06/30/2025

Drug Indication:

For the treatment of attention deficit hyperactivity disorder (ADHD).

Safety Topic:

The FDA requires expanded labeling about weight loss risk in patients younger than 6 years taking extended-release stimulants for ADHD.

Weight Loss Risk in Young Patients Taking Extended-Release Stimulants for ADHD

It is for this reason that we are notifying you that on 06/30/2025 the U.S. Food and Drug Administration (FDA) published a safety communication for all extended-release stimulants indicated to treat attention-deficit/hyperactivity disorder (ADHD) – including certain formulations of amphetamine and methylphenidate.

Reason for Communication:

The FDA is revising the labeling of all extended-release stimulants indicated to treat attention-deficit/hyperactivity disorder (ADHD) - including certain formulations of amphetamine and methylphenidate - to warn about the risk of weight loss and other adverse reactions in patients younger than 6 years taking these medications. Although extended-release stimulants are not approved for children younger than 6 years, healthcare professionals can prescribe them "off-label" to treat ADHD. The FDA now requires a Limitation of Use section in the prescribing information of all extended-release stimulants that includes a statement about the higher plasma exposures and higher rates of adverse reactions in children younger than 6 years.

Pharmacy Required Action:

Advise parents or guardians that they should not discontinue the medication without contacting their healthcare provider. Parents and guardians should ask their healthcare professional about alternative treatments for ADHD. Some immediate-release stimulants are approved for children younger than 6 years.

Assess whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication.

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- ext. 219. Our pharmacists will help you.

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

PharmPix Drug Safety Communication Number COM-2025-040 July 2025

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REFERENCES:

1. U.S. Food and Drug Administration (2025). *FDA requires expanded labeling about weight loss risk in patients younger than 6 years taking extended-release stimulants for ADHD* https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-expanded-labeling-about-weight-loss-risk-patients-younger-6-years-taking-extended

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