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IN THIS ISSUE

In Brief: New Warning for Extended-Release Stimulants for ADHD.....p 135

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IN BRIEF

New Warning for Extended-Release Stimulants for ADHD

The FDA now requires that the labels of all extended-release stimulants used for treatment of attention-deficit/hyperactivity disorder (ADHD) include a warning about the risks of weight loss and other adverse effects associated with their use in children <6 years old. The labels of all stimulants used for treatment of ADHD already contain a boxed warning about the high risk of abuse and dependence associated with their use.

Stimulants (methylphenidate and amphetamines) are the drugs of choice for treatment of ADHD.[1] Long-acting formulations reduce the need for multiple daily doses, which can be advantageous in school-age children and working adults. They are not approved by the FDA for use in children <6 years old, but they are often used off label in these patients.

The new warnings were based on an analysis that found that patients <6 years old with ADHD being treated with extended-release formulations of amphetamine or methylphenidate had higher serum concentrations of the drugs and higher rates of adverse effects, especially clinically significant weight loss, compared to older children taking the same dosage of the same drug.[2]

Patients <6 years old who are taking an extended-release stimulant and have weight loss or other adverse effects should stop taking it or be switched to an immediate-release stimulant. ■

1. Drugs for ADHD. Med Lett Drugs Ther 2020; 62:9.
2. FDA Drug Safety Communication. FDA requires expanded labeling about weight loss risk in patients younger than 6 years taking extended-release stimulants for ADHD. June 30, 2025. Available at: https://bit.ly/4021MWp. Accessed July 30, 2025.

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