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

Action Will Harmonize Labeling Across Extended-Release Stimulant Drug Class

June 30, 2025 FDA Drug Safety Communication

What safety concern is FDA announcing?
The U.S. Food and Drug Administration (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 (side effects) in patients younger than 6 years taking these medications.

Although extended-release stimulants are not approved for children younger than 6 years, health care professionals can prescribe them "off label" to treat ADHD.

FDA has found that patients younger than 6 years taking extended-release stimulants have a greater risk of weight loss and other side effects than older children taking the same medication at the same dosage. The Agency assessed data from clinical trials of extended-release formulations of amphetamine and methylphenidate for ADHD treatment. This analysis found that patients younger than 6 years have higher plasma exposures (i.e., higher levels of the drug in their bodies) and higher rates of side effects than older children. In particular, clinically significant weight loss (at least 10% decrease in the Centers for Disease Control and Prevention (CDC) weight percentile[1]) was observed in both short- and long-term studies with extended-release stimulants. For these reasons, the benefits of extended-release stimulants may not outweigh the risks of these products in patients younger than 6 years with ADHD.

What is FDA doing?
We are requiring 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. Manufacturers of extended-release stimulants that do not have a Limitation of Use section in the labeling will be required to add one about this risk. Manufacturers of extended-release stimulants that already have a Limitation of Use section will be required to revise the labeling to ensure consistent messaging across the drug class.
In the meantime, we want to bring public attention to this risk.

What are extended-release stimulants, and how can they help my child and me?
Extended-release stimulants are prescription drugs primarily used to treat ADHD as first-line (initial) therapy. ADHD is a common childhood disorder that affects the ability to pay attention, follow directions, and complete tasks. It can continue into adulthood. An estimated 7 million (11.4%) of U.S. children 3 to 17 years of age have been diagnosed with ADHD, with boys (15%) more likely to be diagnosed than girls (8%).[2]

Extended-release stimulants come in a variety of dosage forms, including tablets, capsules, transdermal (skin) patches, and liquid suspensions. Most of them are designed to be taken once a day. Common side effects include loss of appetite, weight loss, and insomnia.

What should parents and guardians do?
If parents or guardians notice weight loss in their child taking an extended-release stimulant for ADHD, they should contact their pediatrician or other health care professional to discuss whether the benefits of continued treatment outweigh the risks. Weight loss in young children may contribute to nutritional deficiencies, impaired growth, lower energy levels, and other adverse effects. Parents and guardians can also ask their health care professional about alternative treatments for ADHD. Some immediate-release stimulants are approved for children younger than 6 years. Because immediate-release stimulants do not remain in the body for as long, it may be possible to adjust the timing and frequency of dosing to reduce the negative impacts on appetite and sleep. Behavior therapy can also be an effective way to treat ADHD. Parents and guardians should follow their health care professional's advice about the most appropriate course of action for their child, which may involve changing or stopping the medication.

What should health professionals do?
Health care professionals should be aware that extended-release stimulants are not indicated to treat ADHD in children younger than 6 years because these products have a greater risk of weight loss and other adverse reactions than in older children taking the same dose of the same medication. If a child younger than 6 years is taking an extended-release stimulant and experiencing weight loss or other adverse events, consider stopping the medication and/or switching to an alternative treatment (e.g., immediate-release stimulant). Health care professionals should monitor the child's growth and development and provide necessary interventions to mitigate weight loss. Health care professionals may prescribe other ADHD medications (e.g., immediate-release stimulants) or provide information about behavioral ADHD therapies.

What is my child's risk?
All medicines may have side effects even when used correctly as prescribed. People respond differently to medicines depending on their health, genetic factors, other medicines they are taking, and many other factors. As a result, we cannot determine the likelihood of someone experiencing weight loss or other side effects from taking the medication. Talk to your health care professional(s) if you have questions or concerns about this medication's risks.

How do I report side effects from extended-release stimulants?
To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving extended-release stimulants or other medicines to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.

How can I get new safety information on medicines I'm prescribing or taking?
You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Facts about extended-release stimulants

- Extended-release stimulants are prescription drugs, including certain formulations of amphetamines and methylphenidate, that are primarily used to treat attention-deficit/hyperactivity disorder (ADHD) as first-line (initial) therapy.
- These medications increase the activity of the neurotransmitters dopamine and norepinephrine in areas of the brain associated with attention, executive function, and impulse control.

- They come in a variety of dosage forms, including tablets, capsules, transdermal (skin) patches, and liquid suspensions.
- They are designed to be taken once a day.

Additional Information for Parents and Guardians

- FDA is alerting parents and guardians that children younger than 6 years taking extended-release stimulants have a greater risk of weight loss and other side effects than older children taking the same dosage of the same medication.
- Contact your health care professional if your child is losing weight and talk to them about whether stopping the extended-release stimulant is appropriate and what other ADHD treatments may be available.
- To help FDA track safety issues with medicines, report side effects from extended-release stimulants or other medicines to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines and medical specialties of interest to you.

Additional Information for Health Care Professionals

- Health care professionals should be aware that extended-release stimulants are not indicated to treat ADHD in children younger than 6 years.
- FDA has found that patients younger than 6 years experienced higher plasma exposures and higher rates of adverse reactions than older children taking the same dosage of the same medication.
- For children younger than 6 years experiencing weight loss or other adverse reactions while taking extended-release stimulants, health care professionals should consider stopping the medication and/or switching to an alternative treatment (e.g., immediate-release stimulant).
- Health care professionals may prescribe other medications for ADHD (e.g., immediate-release stimulants) or provide information about behavioral ADHD therapies.
- Health care professionals should monitor the child's growth and development and provide necessary interventions to mitigate weight loss.
- To help FDA track safety issues with medicines, report side effects from extended-release stimulants or other medicines to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines and medical specialties of interest to you.

Data Summary

Through Pediatric Research Equity Act (PREA) postmarketing requirements (PMR), FDA required drug sponsors to evaluate pharmacokinetics (PK), efficacy, and safety of extended-release stimulants in children 4 to 5 years of age. Although the Agency determined that extended-release stimulants are generally safe and effective for older age groups, product labeling for 4 extended-release stimulants include a Limitation of Use statement describing that younger children experienced higher exposures at the same dose relative to older pediatric age groups and higher rates of adverse reactions, including weight loss.

To understand the application of the existing Limitation of Use to all extended-release formulations of amphetamine and methylphenidate, the Agency evaluated differences in PK profiles and exposure-response relationships across pediatric age groups and assessed the short- and long-term effects on weight in children 4 to younger than 6 years of age. Following an assessment of the available clinical trial data in these children, the Agency identified the following:

- Drug exposures were generally higher relative to older children at the same dose
- Higher drug exposures were linked to a greater risk of adverse reactions
- Clinically significant weight loss (at least 10% decrease in the Centers for Disease Control and Prevention (CDC) weight percentile[1]) was observed in both short- and long-term studies with extended-release stimulants
- Findings are consistent for both amphetamine and methylphenidate-containing products

Because the safety profiles for amphetamine and methylphenidate are generally similar and their pharmacodynamic effects are strongly linked to their PK profiles, it is reasonable to expect that that the results of this assessment apply to all formulations of extended-release amphetamine and methylphenidate, and that there is an unfavorable benefit-risk profile for children younger than 6 years taking these medications for ADHD.

References

1. CDC Growth Charts. National Center for Health Statistics. Centers for Disease Control and Prevention. Data extracted September 2024. CDC homepage available at https://www.cdc.gov/growthcharts/cdc-growth-charts.htm
2. Data and Statistics on ADHD. Centers for Disease Control and Prevention. Data extracted November 2024. CDC homepage available at https://www.cdc.gov/adhd/data/index.html

Related Information

- Attention-Deficient/Hyperactivity Disorder (ADHD): Treatment of ADHD
- Cleveland Clinic: ADHD Medication
- Attention-Deficient/Hyperactivity Disorder (ADHD): Data and Statistics on ADHD
- FDA Consumer Update: Treating and Dealing with ADHD

Contact FDA

- For More Info: 855-543-DRUG (3784) and press 4
- druginfo@fda.hhs.gov
- Report a Serious Problem to MedWatch
- Complete and submit the report Online.
- 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.