Safety communication

[23/07/2025]

Risk of Weight Loss in Pediatrics Under 6 Years Taking Extended-Release Stimulants for ADHD.

The Saudi Food and Drug Authority (SFDA) would like to inform healthcare professionals about a recent Safety Labeling Change concerning all extended-release stimulants approved for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in Saudi Arabia**.** This includes products containing methylphenidate and amphetamine derivatives, which are approved for use in children aged 6 years and older**.**

Methylphenidate and lisdexamfetamine act as central nervous system stimulants that increase dopamine and norepinephrine levels in the brain, thereby improve attention and reducing hyperactivity in patients with ADHD.

These products are not approved for children under 6 years of age due to the lack of established safety and efficacy in this population. This information is already reflected in the local Summary of Product Characteristics (SPCs). Recent evidence shows that pediatric patients with ADHD younger than 6 years of age who take extended-release stimulants consistently experience higher plasma drug exposures and more frequent adverse reactions compared to patients 6 years and older when taking the same stimulant dose, including clinically significant weight loss.

As a result, the SFDA has requested the addition of the following text to the local SPC of registered extended-release stimulants.

4.2 Posology and method of administration Pediatric Use section:

Pediatric Use

In studies evaluating extended-release methylphenidate products, patients 4 to <6 years of age experienced higher systemic drug exposures than those observed in older children and adolescents

at the same dose. Pediatric patients 4 to < 6 years of age also experienced elevated rates of adverse reactions, including weight loss.

SFDA Recommendations for Healthcare Professionals:

- Extended-release stimulants are not indicated to treat ADHD in children younger than 6 years.
- Patients younger than 6 years who take extended-release stimulants may experience higher plasma exposures and higher rates of adverse reactions than older children taking the same dosage of the same medication.
- Monitor growth and development in all children taking extended-release stimulants.
- Counsel caregivers to report any signs of weight loss, reduced appetite, growth suppression, or lower energy levels.

List of Registered Extended-Release Stimulant Products in Saudi Arabia:

Drug Name	Trade Name	MAH
Lisdexamfetamine Dimesilate	VYVANSE	Takeda Pharmaceuticals
Methylphenidate	CONCERTA	Janssen
Methylphenidate	CONCENTIA	Exeltis Healthcare S. L
Methylphenidate	QUILLIVANT XR	SPIMACO
Methylphenidate	RITALIN	Novartis Saudi Limited

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Call Center: 19999

Website: https://ade.sfda.gov.sa

SFDA RMM Webpage: