NEW FORMULATION

Extended-release, orally disintegrating mixed amphetamine salts for ADHD

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An amphetamine-based, extended-release, orally disintegrating tablet for patients age ≥6 diagnosed with attention-deficit/hyperactivity disorder (ADHD) won FDA approval on January 28, 2016 (***Table***).[1]

Adzenys XR-ODT is the first extended-release, orally disintegrating tablet for ADHD, Neos Therapeutics, Inc. the drug's manufacturer, said in a statement.[2] The newly approved agent is bioequivalent to Adderall XR (the capsule form of extended-release mixed amphetamine salts), and patients taking Adderall XR can be switched to the new drug. Equivalent dosages of the 2 drugs are outlined on the prescribing information.[1]

"The novel features of an extended-release orally disintegrating tablet ... make Adzenys XR-ODT attractive for use in both children (6 and older) and adults," Alice R. Mao, MD, Medical Director, Memorial Park Psychiatry, Houston, Texas, said in the statement.[2]

As a condition of the approval, Neos must annually report the status of 3 post-marketing studies of children diagnosed with ADHD taking Adzenys XR-ODT, according to the approval letter.[2] One is a single-dose, open-label study of children ages 4 and 5; the second is a randomized, double-blind, placebo-controlled titration study of children ages 4 and 5; and the third is a 1-year, open-label safety study of patients ages 4 and 5.

For patients age 6 to 17, the starting dosage is 6.3 mg once daily in the morning; for adults, it is 12.5 mg once daily in the morning, according to the label.[1] The medication will be available in 4 other dose strengths: 3.1 mg, 9.4 mg, 15.7 mg, and 18.8 mg.

The most common adverse reactions to the drug among pediatric patients include loss of appetite, insomnia, and abdominal pain. Among adult patients, adverse reactions include dry mouth, loss of appetite, and insomnia.

Table

Fast facts about extended-release, orally disintegrating mixed amphetamine salts

Brand name: Adzenys XR-ODT
Class: CNS stimulant
Indication: Attention-deficit/hyperactivity disorder, patients age ≥6
Approval date: January 28, 2016
Availability date: Second quarter of 2016
Manufacturer: Neos Therapeutics, Inc.
Dosing forms: 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg, 18.8 mg
Recommended dosages: 6.3 mg starting dosage, once daily in the morning (children age 6 to 17); 12.5 mg starting dosage, once daily in the morning (adults)

Patients taking the capsule form of extended-release mixed amphetamine salts can be switched to this new orally disintegrating formulation, which is bioequivalent

References

1. Adzenys XR-ODT [prescription packet]. Grand Prairie, TX: Neos Therapeutics, LP; 2016.
2. Neos Therapeutics announces FDA approval of Adzenys XR-ODT (amphetamine extended-release orally disintegrating tablet) for the treatment of ADHD in patients 6 years and older [news release]. Dallas, TX: Neos Therapeutics, Inc; January 27, 2016. http://investors.neostx.com/phoenix.zhtml?c=254075&p=RssLanding&cat=news&id=2132931. Accessed February 3, 2016.

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