For pediatric attention-deficit/hyperactivity disorder (ADHD)

Treating ADHD in Elementary School Children

Case Study 1: Have You Seen Jacob?

DO YOU HAVE ELEMENTARY SCHOOL PATIENTS EXHIBITING ANY OF THE FOLLOWING?

- Disruptive classroom behavior?
- Inability to complete tasks?
- Difficulty keeping emotions in check?

Meet Jacob*—a 6-year-old kindergarten student

HISTORY:
- Jacob’s mother describes him as “full of energy”
- His teacher reports Jacob has difficulty sitting still and is distracting others in class
- Jacob admits to losing things often and is unable to pay attention to his teachers or parents

CLINICAL OBSERVATIONS\(^2\):
- Does the patient seem restless or unable to control impulses?
- Can the patient pay attention to your direct questions?
- Is the patient interrupting the conversation and blurting out excessively?
- Does the patient appear frustrated or distracted?

*Patient portrayal.

It may be time for a change: Consider Evekeo as part of a total ADHD treatment program\(^3\)

INDICATION

Evekeo® CII (amphetamine sulfate tablets, USP) is a prescription medicine for the treatment of narcolepsy, attention deficit disorder with hyperactivity as an integral part of a total treatment program and exogenous obesity as a short term adjunct in a regimen of weight reduction.

IMPORTANT SAFETY INFORMATION

Evekeo is a federally controlled substance (CII) with a high risk of abuse or dependence. Prolonged use may lead to drug dependence and must be avoided. Subjects may obtain Evekeo for illegal non-therapeutic use or distribution to others, and therefore it should be prescribed or dispensed sparingly. Misuse of Evekeo may cause sudden death and serious cardiovascular adverse events.

Please see additional Important Safety Information on reverse side and accompanying full Prescribing Information, including Boxed Warning regarding abuse and dependence.
Evekeo demonstrated significant improvement of SKAMP-Combined scores compared with placebo

**Evekeo: SKAMP-Combined**

- A single morning dose of Evekeo at 8 AM demonstrated significant efficacy (P<0.0001) vs placebo at all measured time points from 45 minutes through 10 hours post dose

**INDICATION**

Evekeo® (amphetamine sulfate tablets, USP) is a prescription medicine for the treatment of narcolepsy, attention deficit disorder with hyperactivity as an integral part of a total treatment program and exogenous obesity as a short term adjunct in a regimen of weight reduction.

**IMPORTANT SAFETY INFORMATION**

Evekeo is a federally controlled substance (CII) with a high risk of abuse or dependence. Prolonged use may lead to drug dependence and must be avoided. Subjects may obtain Evekeo for illegal non-therapeutic use or distribution to others, and therefore it should be prescribed or dispensed sparingly. Misuse of Evekeo may cause sudden death and serious cardiovascular adverse events.

**Contraindications**

Evekeo is contraindicated in patients:

- with a history of advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines
- that are tense or agitated
- with a history of drug abuse
- taking, or who have taken, monoamine oxidase inhibitor (MAOI) within 14 days. Hypertensive crises may result.

**Warnings and Precautions**

Sudden death has been reported in children and adolescents with structural cardiac abnormalities or other serious heart problems in association with CNS stimulant treatment at usual doses. Sudden death, stroke or myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Stimulant medications can cause an increase in blood pressure (mean increase about 2-4 mmHg) and heart rate (mean increase about 3-6 bpm). All patients should be monitored for larger changes in heart rate and blood pressure.

Children, adolescents, or adults who are being considered for treatment with Evekeo should have a careful history (including assessment for a family history of sudden death or ventricular arrhythmia) and physical exam to assess for the presence of cardiac disease. Patients developing any signs of heart problems such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease while taking Evekeo should undergo a prompt cardiac evaluation.

Stimulants may exacerbate symptoms in patients with pre-existing psychotic or manic symptoms or in patients with new or worsening bipolar disorder. Treatment-emergent psychotic or manic symptoms can occur in children or adolescents such as hallucinations, delusional thinking, or mania. Aggressive behavior or hostility is also often observed in children and adolescents taking medicines for ADHD and should be monitored for the appearance of, or worsening of aggressive behavior or hostility.

Stimulants have been associated with long-term suppression of growth in pediatric patients. Growth should be monitored during treatment with Evekeo, and patients not growing or gaining height or weight as expected may need to have their treatment interrupted.

Stimulants may lower the convulsive threshold in patients with prior history of seizures, in patients with prior EEG abnormalities in absence of seizures, and, very rarely, in patients without a history of seizures and no prior EEG evidence of seizures. In the presence of seizures, the drug should be discontinued.

**Serotonin syndrome**

Serotonin syndrome, a potentially life-threatening reaction, may occur when amphetamines are used in combination with other drugs that affect the serotonergic neurotransmitter systems such as MAOIs, SSRIS, SNRIS, triptans, triyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John’s Wort. See DRUG INTERACTIONS in the prescribing information for all Evekeo interactions. The potential for a pharmacokinetic interaction exists with the co-administration of CYP2D6 inhibitors which may increase the risk with increased exposure to Evekeo. In these situations, consider an alternative non-serotonergic drug or an alternative drug that does not inhibit CYP2D6.

Serotonin syndrome symptoms may include mental status changes, autonomic instability, neuromuscular symptoms, seizures, and/or gastrointestinal symptoms. Concomitant use of Evekeo with MAOI drugs is contraindicated. Discontinue treatment with Evekeo and any concomitant serotonergic agents immediately if the above symptoms occur, and initiate supportive symptomatic treatment. If concomitant use of Evekeo with other serotonergic drugs or CYP2D6 inhibitors is clinically warranted, initiate Evekeo with lower doses, monitor patients for the emergence of serotonin syndrome during drug initiation or titration, and inform patients of the increased risk for serotonin syndrome.

**Adverse Reactions**

The most common side effects reported with Evekeo treatment include palpitations, tachycardia, hypertension, cardiomyopathy (with chronic use), overstimulation, restlessness, dizziness, insomnia, euphoria, dyskinesia, dysphoria, tremor, headache, exacerbation of phonic tics and Tourette’s syndrome, dry mouth, unpleasant taste, constipation, gastrointestinal disturbances, anorexia and weight loss, urticaria, impotence, changes in libido, frequent or prolonged erections, and rhabdomyolysis.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For additional safety information, consult the Evekeo full Prescribing Information and Medication Guide.

**References:**


Evekeo is a registered trademark of Arbor Pharmaceuticals, LLC © 2017 Arbor Pharmaceuticals, LLC. All rights reserved.

PP-EVE-US-0372 March 2017