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

**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.

**It may be time for a change: Consider Evekeo as part of a total ADHD treatment program**

---

*Patient portrayal.
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.

**Study details:** SKAMP-combined measurement includes attention, deportment, quality of work, and compliance subscales, and is a standardized, validated classroom assessment tool consisting of 13 items used for evaluating inattention and behavioral symptoms of ADHD.

---

**INDICATION**

Evekeo® (amphetamine sulfate tablets, USP) is a prescription medicine for the treatment of attention-deficit/hyperactivity 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 purposes 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 using MAO inhibitors (MAOIs) or taking or using 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, and 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 arrhythmias) 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 psychiatric disorder 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 medications 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 the presence of seizures, the drug should be discontinued.

Stimulants used to treat ADHD are associated with peripheral vasculopathy, including Raynaud’s phenomenon. Signs and symptoms are usually intermittent and mild; however, very rare sequelae include digital ulceration and/or soft tissue breakdown. Effects were observed in post-marketing reports at different times and at therapeutic doses in all age groups throughout the course of treatment. Signs and symptoms generally improve after reduction in dose or discontinuation of drug. Careful observation for digital changes is necessary during treatment with ADHD stimulants. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients.

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, restlessess, 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:**

3. Evekeo [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC.

Evekeo is a registered trademark of Arbor Pharmaceuticals, LLC © 2017 Arbor Pharmaceuticals, LLC. All rights reserved. PP-EVE-US-0372 March 2017
**EVEKEO** (amphetamine sulfate tablets, USP)

**WARNINGS**

AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE, DEPENDENCE, AND ADDICTION. THE RISK OF DEPENDENCE OR ABUSETHE RISK OF DEPENDENCE OR ABUSE INCREASES WITH THE LENGTH OF USE, THE DOSE USED, AND THE FREQUENCY OF USE. THOSE chase and consume other amphetamine-like stimulants. Initially, in some clinical populations, amphetamine sulfate may be slightly more addictive than benzphetamine. If a patient has been taking stimulant drugs or other drugs for a prolonged period, the abrupt withdrawal of the drug may result in potentially serious and sometimes fatal consequences.

**DESCRIPTION**

Amphetamine Sulfate is a sympathomimetic amine of the amphetamine group. It is a white, odorless crystalline powder. It has a slightly better taste. Its solutions are acidic to litmus, have a pH of 1.5 to 2.5, and are slightly soluble in alcohol and practically insoluble in water.

Each tablet for oral administration contains 5 mg or 10 mg of amphetamine sulfate, USP, and the following inactive ingredients: crospovidone, silicified microcrystalline cellulose, andFD&C Blue #1.

**INDICATIONS AND USAGE**

The primary use of amphetamine sulfate is for the relief of fatigue and lethargy in patients suffering from narcolepsy. Although narcolepsy is a sleep disorder, its treatment is similar to that of other types of depression. Amphetamine is also prescribed for the treatment of obesity. However, the natural history of obesity is measured in years, whereas the natural history of narcolepsy is measured in days.

**CLINICAL PHARMACOLOGY**

Amphetamine is a sympathomimetic amine with CNS stimulant activity. Peripheral actions include increased peripheral vasoconstriction, increased blood pressure, and increased heart rate; bronchodilation; and increased blood sugar levels.


**Medical Information**

**Evekeo** (amphetamine sulfate tablets, USP)

Read this Medication Guide before you or your child starts taking Evekeo and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor or pharmacist about your treatment.

What is the most important information I should know about Evekeo tablets?

**Evekeo** is a stimulant medicine. Some people have had the following serious problems when taking stimulant medicines such as Evekeo:

1. **Heart-related problems:**
   - sudden death of people who have heart problems or heart defects
   - stroke and heart attack in adults
   - increased blood pressure and heart rate
   Tell your doctor if you or your child has any heart problems, heart defects, high blood pressure, or a family history of these problems.
   Your doctor should check you or your child carefully for heart problems before starting Evekeo.
   Your doctor should check your child’s blood pressure and heart rate regularly during treatment with Evekeo.

2. **Mental (Psychiatric) problems including:
   - new or worse aggressive behavior or hostility
   In Children and Teenagers who have psychiatric problems, new psychiatric symptoms such as:
   - hearing things that are not real
   - believing things that are not real
   - new manic symptoms
   Tell your doctor about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

3. **Circumstantial problems in fingers and toes**
   (Paradoxical reactions), including:
   - floating or tingly feelings
   - fingers or toes may feel numb, cool, painful
   - fingers or toes may change color from pale to blue, to red
   
   Tell your doctor if you or your child has numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.

Call your doctor right away if you or your child have any new or worsening mental problems while taking Evekeo, especially:
- seeing or hearing things that are not real
- believing things that are not real

Tell your doctor if:
- you or your child are pregnant or planning to become pregnant. It is not known if Evekeo will harm your unborn baby.
- you or your child are breastfeeding or plan to breastfeed. Evekeo can pass into your milk and may harm your baby. Talk to your doctor about the best way to feed your baby if you take Evekeo. Do not breastfeed while taking Evekeo.

Tell your doctor about all the medicines that you or your child takes, including prescription and nonprescription medicines, vitamins, and herbal medicine. Evekeo and some medicines may interact with each other and cause serious side effects. Sometimes the doctor of other medicines will need to be adjusted while taking Evekeo.

Your doctor will decide whether Evekeo can be taken with other medicines.

Tell your doctor or pharmacist if you or your child:
- have used Evekeo in the past
- have used or are using any other medicines (prescription or nonprescription)
- have used or are using any herbal medicine

What is Evekeo?

**Evekeo** is a central nervous system stimulant prescription medicine used for the treatment of:
- a sleep disorder called narcolepsy.

**Attention-Deficit Hyperactivity Disorder (ADHD):**
Evekeo may help increase attention and decrease impulsiveness and hyperactivity in children with ADHD. Evekeo should be used as part of a total treatment program for ADHD that may include counseling or other therapies.
**Excessive obesity:**
Evekeo may be used as part of a short-term, weight reduction program for obesity.
**Evekeo** is not for use as an anorectic agent for excessive obesity in children less than 12 years of age.
**Evekeo** is not for use in ADHD children less than 3 years old.

The effects of long term use of Evekeo in children are not known.

Evekeo is a federally controlled substance (CII) because it contains amphetamine which can be a target for people who abuse prescription medicines or street drugs. Keep in a safe place to protect it from theft. Never give your Evekeo to anyone else, because it may cause death or harm them. Selling or giving away Evekeo is against the law.

Tell your doctor if you or your child has any of these medical problems:
- high blood pressure
- heart problems
- very anxious, tense, or agitated
- a history of severe high blood pressure
- have a history of drug abuse
- are taking or have taken within the past 14 days an anti-depressant medicine called a monoamine oxidase inhibitor or MAO
- are sensitive to, allergic to, or have had a reaction to other stimulant medicines

What should I tell my doctor before taking Evekeo?

Before you or your child takes Evekeo, tell your doctor if you or your child has or if there is a family history of:
- heart problems, heart defects, high blood pressure
- mental problems including psychosis, manic, bipolar illness, or depression
- rash or Tourniquet’s syndrome
- thyroid problems
- seizures or have had an abnormal brain wave test in a hospital emergency room.
- changes in mental status
- slowing of growth (height and weight) in children

Tell your doctor if you or your child are:
- taking other medicines
- taking medicine for a condition you did not list

If you or your child takes too much Evekeo, call your doctor right away, or go to the nearest hospital emergency room.

What should I avoid while taking Eveko?

Do not drive, operate machinery, or do any other dangerous activities until you know how Evekeo affects you.

What are the possible side effects of Evekeo?

Evekeo may cause serious side effects, including:

- headache
- stomach ache
- trouble sleeping
- decreased appetite
- unpleasant taste
- nervousness
- trouble sleeping
- sexual problems (impotence in males)
- itching
- dizziness
- constipation
- dry mouth
- weight loss
- most side effects

Talk to your doctor if you or your child have side effects that are bothersome or do not go away. These are not all the possible side effects of Evekeo. For more information ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to Arbor Pharmaceuticals, LLC, Medical Information at 1-866-516-4950 or FDA at 1-800-FDA-1088.

How should I store Evekeo?

Store at room temperature between 25°C to 70°F (0°C to 25°C).
Keep Evekeo and all medicines out of the reach of children.

General Information about the safe and effective use of Evekeo.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use a medicine for a condition for which it was not prescribed. Do not give medicines to other people, even if they have the same condition. It may harm them and cause serious side effects.

This Medication Guide summarizes the most important information about Evekeo. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Evekeo that was written for healthcare professionals.

For more information about Evekeo, please contact Arbor Pharmaceuticals, LLC at 1-800-516-4950.

What are the ingredients in Evekeo?

**Active ingredient:** amphetamine sulfate

**Inactive ingredients:** crospovidone, sugar, microcrystalline cellulose, and stearic acid.

The 10 mg tablets also contain PEG 4001.

**This Medication Guide has been approved by the U.S. Food and Drug Administration.**

Manufactured by:

Mikart, Inc.
Atlanta, GA 30318

Manufactured for:

Arbor Pharmaceuticals, LLC
Atlanta, GA 30318

Rev: 09/16

**AM-MS-06**

**AM-Pr-06**

**AM-PI-08**

**AM-PI-08**

**AM-PI-08**

**AM-PI-08**

**AM-PI-08**

**AM-PI-08**

**AM-PI-08**

**AM-PI-08**

**AM-PI-08**