Amphetamines are non-catecholamine, sympathomimetic amines with CNS stimulant activity. Peripheral actions include elevations of systolic and diastolic blood pressures, and weak increases in heart rate. Amphetamines, as the racemic form, differs from dehydroamphetamine in a number of ways. The i, more potent isomer the d, is not as potent in classic cardiovascular activity, but much less potent in causing CNS excitatory effects. Amphetamine also differs from other CNS stimulants in its ability to produce mild to moderate behavioral changes such as alertness or arousal. It is unknown whether this ability is unique to amphetamine or to some other CNS stimulants. Amphetamines are also unique in their ability to produce a wide range of behavioral changes in response to different doses. Studies do not permit conclusions as to the relative importance of the drug and non-drug factors on weight loss. The natural history of obesity is measured in years, whereas the studies cited are restricted to a few weeks duration; thus, the impact of drug-induced weight loss would not be of diet alone must be considered clinically limited.

INDICATIONS AND USAGE

Evekeo® (amphetamine sulfate tablets, USP) is indicated for:

1. Narcolepsy

2. Attention Deficit Disorder with Hyperactivity as a integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with behavioral syndrome characterized by the following group of developmental inappropriate symptoms: severe to moderate distractibility, short attention span, hyperactivity, emotional lability, impulsivity. The diagnosis of the syndrome should not be made with facility when these symptoms are of only comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disorders, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dys�unction may or may not be warranted. Patients with symptoms of a drug abuse history. During or within 14 days following the administration of monoamine oxidase inhibitors (hypertensive crises may result).

WARNING

Serious Cardiovascular Events

Suicidal and Aggressive Behavior

Structural Cardiac Abnormalities or Other Serious Heart Problems

Children and Adolescents

- Suicide death has been reported in association CNS stimulant treatment of usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Although some cases are known to carry an increased risk of sudden death, stimulant products generally should not be used in children or adolescents with known or suspected structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased vulnerability to the serious cardiovascular effects of a stimulant drug. (see CONTRAINDICATIONS). Adults – Suicide deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. The risk of the stimulants in these adults may be greater than that of children because adults have a greater likelihood than children of having serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems. Adults who abuse stimulants should also generally not be treated with stimulant drugs (see CONTRAINDICATIONS).

Hypertension and Other Cardiovascular Conditions

- Amphetamines are a modified form in average blood pressure (about 2 to 4 mm Hg) and average heart rate (about 3 to 6 bpm), and individuals may have larger increases. While the mean increases are smaller than those with hypertension, these effects are not expected to cause large increases in blood pressure and are usually not associated with any adverse effects on the cardiovascular system.

- A history of hypertension should be considered in patients with hypertension, hypercholesterolemia, or obesity. Patients with hypertension, hypercholesterolemia, or obesity should be monitored for the development of increased blood pressure and possibly other adverse effects on the cardiovascular system. (see CONTRAINDICATIONS).

- Antidepressant Stabilizing Patients in Behaviors Treated with Stimulant Medications

- Children and adolescents who are being considered for treatment with stimulant medications should have a careful history (including assessment for a family history of sudden death or cardiac arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further cardiac evaluation if findings suggest such a possibility. Psychotropic agents such as serotonergic antidepressants, selective serotonin reuptake inhibitors, and/or other stimulants, may contribute to the development of arrhythmias, including both premature ventricular contractions andqt prolongation. It is recommended that these patients have baseline electrocardiograms performed and monitored for any changes that develop after stimulant initiation.

CLINICAL PHARMACOLOGY

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Evekeo** (amphetamine sulfate tablets, USP) is supplied as follows:

5 mg: white, round tablet, debossed “EVK” on one side, and “1” with a score on the other side in bottles of 100 tablets, NDC 24338-020-10.

10 mg: blue, round tablet, debossed “EVK” on one side, and “10” with double scores on the other side in bottles of 100 tablets, NDC 24338-020-10. Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature] Dispense in a well-closed container, as defined in the USP.

Manufactured by:

Mikart, Inc.
Atlanta, GA 30318

Manufactured for:

Arbor Pharmaceuticals, LLC
Atlanta, GA 30328

AMM-P08
11BDD0
Rev. 09/16

MEDICATION GUIDE

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 about you or your child’s treatment.

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 impulsive and hyperactivity in patients 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 for ADHD in children less than 3 years old.

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

Who should not take Evekeo?

Do not take Evekeo if you or your child:

- have heart problems or hardening of the arteries
- have moderate to severe high blood pressure
- have hypertension
- are very anxious, tense, or agitated
- have a history of drug abuse
- are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor (MAOI)
- are sensitive to, allergic to, or have had a reaction to other stimulant medicines

Tell your doctor if you or your child has or has had:

- a history of heart defects, high blood pressure, or mental problems including psychosis, mania, bipolar illness, or depression
- tics or Tourette’s syndrome
- thyroid disorders
- seizures or have had an abnormal brain wave test (EEG)
- circulation problems in fingers and toes

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 supplements. Evekeo may interact with other medicines and cause serious side effects.

Sometimes the doses of other medicines will need to be adjusted while taking Evekeo. Your doctor will decide whether Evekeo can be taken with other medicines. Especially tell your doctor if you or your child takes:

- anti-depressant medicines including MAOIs
- antipsychotic medicines
- lithium
- cold or allergy medicines that contain decongestants
- blood pressure medicines
- narcotic pain medicines
- seizure medicines
- blood thinner medicines

Know the medicines that you or your child takes.

Keep a list of your medicines with you to show your doctor and pharmacist when you get a refill. Take all the medicines that you or your child is taking. Do not start any new medicine while taking Evekeo without talking to your doctor first. How should I take Evekeo?

- Take Evekeo exactly as your doctor tells you to take it.
- Your doctor may change the dose until it is right for you or your child.
- The first dose of the day is usually taken when you first wake in the morning. Evekeo may cause problems sleeping if taken late at night.
- Evekeo can be taken with or without food.
- From time to time, your doctor may stop Evekeo treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking Evekeo.
- Children should have their height and weight checked often while taking Eveko.
- Evekeo treatment may be stopped if a problem is found during these check-ups.
- If you or your child take too much Eveko, call your doctor right away, or go to the nearest hospital emergency room.

What should I avoid while taking Evekeo?

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

What are possible side effects of Evekeo?

Evekeo may cause serious side effects, including:

- See “What is the most important information I should know about Eveko?” for information on reported heart and mental problems.

Other serious side effects include:

- Slowing of growth (height and weight) in children
- seizures, mainly in people with a history of seizures
- eye sight changes or blurred vision
- osteoporosis. A potentially life-threatening problem called serotonin syndrome can
- analgesics, narcotics, or other changes in mental status
- problems controlling your movements or muscle twitching
- fast heart rate
- high or low blood pressure
- sweating or fever
- nausea or vomiting
- shakiness or trembling
- muscle stiffness or tightening

Manufactured by:

Arbor Pharmaceuticals, LLC
Atlanta, GA 30302

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