DESCRIPTION
Amphetamine Sulfate is a sympathomimetic amines of the amphetamine group. It is a white, odorless, bitter-tasting solid. It is soluble in water, slightly soluble in alcohol and practically insoluble in ether.

Amphetamine, as the racemic form, differs from desmethyldextroamphetamine in a number of ways. Drugs related to amphetamine are commonly known as “anorexigens” or “anorectics.”

- It has not been established, however, that the action of such drugs in treating obesity is primarily due to their suppressor effects on the central nervous system. Thus, the possible stimulant or other psychological effects may be involved, for example. Adult obese subjects instructed in dietary management and treated with “anorectic” drugs lose more weight on the average than these treated with placebo, as determined in relatively short-term clinical trials.

- The magnitude of increased weight loss of drug-treated patients over placebo-treated patients is only about 1/2 to 1 kg per week. The maximum weight loss is the first weight recorded in the first week. The weight loss is not sustained after the discontinuation of therapy for both drug and placebo subjects and tends to decrease in succeeding weeks. The origins of the increased weight loss due to the possible variable effects are not established. The amount of weight associated with the use of an “anorectic” drug varies from trial to trial, and the increased weight loss appears to be related in part to variables other than the drug prescribed, such as the nature of the diet prescribed.

- The limited usefulness of amphetamines as anorectic agents cannot be weighed against possible risks inherent in the use of the drug, such as those described below.

CONTRAINDICATIONS
- Amphetamines are contraindicated in patients with a history of drug abuse.

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

1. Nauscepy

2. Attention Deficit Disorder with Hyperactivity as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with behavior disorders characterized by the following constellation of developmenal, inappropriate symptoms: severe to moderate distractibility, attention span, hyperactivity, emotional lability, and impulsivity. The diagnosis of the syndrome should not be made with facility when these symptoms are not of comparatively recent origin. Nonclinical (soo) psychologic, learning disabilities, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or may not be warranted.

3. Exogenous Obesity as a short-term (at a few weeks) adjunct in a regime of weight reduction measures, such as diet therapy, behavioral therapy, and exercise programs. Diets, weight loss programs, and other drugs. The limited usefulness of amphetamines as anorectic agents cannot be weighed against possible risks inherent in the use of the drug, such as those described below.

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Medication Guide

Evekeo® (amphetamine sulfate tablets, USP)

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

What is Evekeo?

Evekeo is a stimulant medicine. People who have had the following problems when taking stimulant medicines such as Evekeo:

1. Heart-related problems:
   - sudden death in people who have heart problems or heart defects
   - stroke and heart attack in adults

Tell your doctor if you or your child has any heart problems, heart defects, high blood pressure, or a family history of these problems.

Tell your doctor if your child has any heart problems, heart defects, high blood pressure, or a family history of these problems before starting Evekeo.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with Evekeo.

Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Evekeo.

2. Mental (Psychiatric) problems including:

   a. new or worse behavior and thought problems
   - new or worse bipolar illness
   - new or worse aggressive behavior or hostility

In Children and Teenagers who have psychiatric problems, new psychiatric symptoms such as:

   a. hearing voices
   - seeing things that are not real
   - believing things that are not true
   - being suspicious
   - 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.

Call your doctor right away if you or your child have any new or worsening mental symptoms or problems while taking Evekeo, especially:

   a. seeing or hearing things that are not real
   - believing things that are not real
   - being suspicious

3. Circulation problems in fingers and toes (Peripheral vasculopathy, including Raynaud’s phenomenon):

   a. Fingertips 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 has any signs of unexplained wounds appearing on fingers or toes while taking Evekeo.

The most common side effects of Evekeo include:

   a. headache
   b. stomach ache
   c. trouble sleeping
   d. decreased appetite
   e. weight gain
   f. dry mouth
   g. weight loss
   h. mood swings

Talk to your doctor if you or your child has 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 Evekeo at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep Evekeo and all medications 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 Evekeo for a condition for which it was not prescribed. Do not give Evekeo to other people, even if they have the same condition. It may harm them and it is against the law.

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 1-866-516-4950.

What are the ingredients in Evekeo?

Active Ingredient: amphetamine sulfate

Inactive Ingredients: croscarmellose sodium, microcrystalline cellulose, and stearic acid.

The 10 mg tablets also contain FD&C Blue #1.

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 30328

AM-MG-06 Rev. 09/16

REV. 09/16

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