

Symptoms

Manifestations of acute overdosage with amphetamines include restlessness, tremor, hyperreflexia, rhabdomyolysis, rapid respiration, hyperpyrexia, confusion, assaultiveness, hallucinations, panic states. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmias, hypertension, or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning is usually preceded by convulsions and coma.

Treatment

Management of acute amphetamine intoxication is largely symptomatic and includes gastric lavage and sedation with a barbiturate. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard. Acidification of the urine increases amphetamine excretion. If acute, severe hypertension complicates amphetamine overdosage, administration of intravenous phentolamine has been suggested. However, a gradual drop in blood pressure will usually result when sufficient sedation has been achieved. Chlorpromazine antagonizes the central stimulant effects of amphetamines and can be used to treat amphetamine intoxication.

DOSAGE AND ADMINISTRATION

Regardless of indication, amphetamine should be administered at the lowest effective dosage and dosage should be individually adjusted. Late evening doses should be avoided because of resulting insomnia.

Narcolepsy

Usual dose is 5 to 60 milligrams per day in divided doses depending on the individual patient response.

Narcolepsy seldom occurs in children under 12 years of age; however, when it does, Evekeo may be used. The suggested initial dose for patients aged 6 to 12 is 5 mg daily; daily dose may be raised in increments of 5 mg at weekly intervals until optimal response obtained. In patients 12 years of age and older, start with 10 mg daily; daily dosage may be raised in increments of 10 mg at weekly intervals until optimal response is obtained. If bothersome adverse reactions appear (e.g., insomnia or anorexia) dosage should be reduced. Give the first dose on awakening; additional doses (5 or 10 mg) at intervals of 4 to 6 hours.

Attention Deficit Disorder with Hyperactivity

Not recommended for children under 3 years of age.

In children from 3 to 5 years of age, start with 2.5 mg daily; daily dosage may be raised in increments of 2.5 mg at weekly intervals until optimal response is obtained.

In children 6 years of age or older, start with 5 mg once or twice daily; daily dosage may be raised in increments of 5 mg at weekly intervals until optimal response is obtained. Only in rare cases will it be necessary to exceed a total of 40 milligrams per day.

With tablets give first dose on awakening; additional doses (1 to 2) at intervals of 4 to 6 hours.

Where possible, drug administration should be interrupted occasionally to determine if there is a recurrence of behavioral symptoms sufficient to require continued therapy.

Exogenous Obesity

Usual dosage is up to 30 mg daily, taken in divided doses of 5 to 10 mg, 30 to 60 minutes before meals. Not recommended for this use in children under 12 years of age.

HOW SUPPLIED

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

5 mg: White, round tablet, debossed "EVK" on one side, and "5" with a score on the other side in bottles of 100 tablets, NDC 24338-022-10.

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 24338-026-10.

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



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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 the most important information I should know about Evekeo tablets?
Evekeo is a stimulant medicine. Some people 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
- 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 you or your child's blood pressure and heart rate regularly during treatment with Evekeo.

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

2. Mental (Psychiatric) problems including:

In children, teenagers, and adults:

- 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 psychotic symptoms such as:

- 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:

- 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].

- 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 have 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 have or your child has any signs of unexplained wounds appearing on fingers or toes while taking Evekeo.

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 patients with ADHD. Evekeo should be used as part of a total treatment program for ADHD that may include counseling or other therapies.
 - exogenous 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 exogenous 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.

Evekeo is a federally controlled substance (CII) because it contains amphetamine that can be a target for people who abuse prescription medicines or street drugs. Keep Evekeo 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 (or has a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

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 hyperthyroidism
- 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 or MAOI
- are sensitive to, allergic to, or 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, mania, bipolar illness, or depression
- tics or Tourette's syndrome
- thyroid problems
- 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 and some medicines may interact with each other 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:

- stomach acid medicines
- anti-depression medicines including MAOIs
- anti-psychotic 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 new medicine.

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 Evekeo. Evekeo treatment may be stopped if a problem is found during these check-ups.
- 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 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 Evekeo?" 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
- eyesight changes or blurred vision
- Serotonin syndrome. A potentially life-threatening problem called serotonin syndrome can happen when medicines such as Evekeo are taken with certain other medicines. Symptoms of serotonin syndrome may include:
 - agitation, hallucinations, coma or other changes in mental status
 - problems controlling your movements or muscle twitching
 - fast heartbeat
 - high or low blood pressure
 - sweating or fever
 - nausea or vomiting
 - diarrhea
 - muscle stiffness or tightness

The most common side effects of Evekeo include:

- headache
- stomach ache
- trouble sleeping
- decreased appetite
- unpleasant taste
- nervousness
- dizziness
- sexual problems (impotence in males)
- vomiting
- itching
- diarrhea or constipation
- dry mouth
- weight loss
- mood swings

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 Evekeo at room temperature between 68°F to 77°F (20°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 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: crospovidone, silicified 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.

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