

## MEDICATION GUIDE

### Amphetamine Sulfate Tablets (am fet' a meen sul' fate)

Read this Medication Guide before you or your child starts taking amphetamine sulfate tablets 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 amphetamine sulfate tablets?**

**Amphetamine sulfate tablet is a stimulant medicine. Some people have had the following problems when taking stimulant medicines such as amphetamine sulfate tablets:**

##### **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 amphetamine sulfate tablets.

Your doctor should check you or your child's blood pressure and heart rate regularly during treatment with amphetamine sulfate tablets.

**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 amphetamine sulfate tablets.**

##### **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 amphetamine sulfate tablets, 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 amphetamine sulfate tablets.**

**What are amphetamine sulfate tablets?**

- Amphetamine sulfate tablets are central nervous system stimulant prescription medicine used for the treatment of:
  - a sleep disorder called narcolepsy.
  - **Attention-Deficit Hyperactivity Disorder (ADHD).** Amphetamine sulfate tablets may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD. Amphetamine sulfate tablets should be used as part of a total treatment program for ADHD that may include counseling or other therapies.
  - **exogenous obesity.** Amphetamine sulfate tablets may be used as part of a short-term, weight reduction program for obesity.
- Amphetamine sulfate tablets are not for use as an anorectic agent for exogenous obesity in children less than 12 years of age.
- Amphetamine sulfate tablets are not for use for ADHD in children less than 3 years old.
- The effects of long-term use of amphetamine sulfate tablets in children are not known.

**Amphetamine sulfate tablet 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 amphetamine sulfate tablets in a safe place to protect it from theft. Never give your amphetamine sulfate tablets to anyone else, because it may cause death or harm them. Selling or giving away Amphetamine sulfate tablets are 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 amphetamine sulfate tablets?**

**Do not take amphetamine sulfate tablets 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 amphetamine sulfate tablets?**

#### **Before you or your child takes amphetamine sulfate tablets, 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 amphetamine sulfate tablets will harm your unborn baby.
- you or your child are breastfeeding or plan to breastfeed. Amphetamine sulfate 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 amphetamine sulfate tablets. Do not breastfeed while taking Amphetamine sulfate tablets.

#### **Tell your doctor about all the medicines that you or your child takes, including prescription and nonprescription medicines, vitamins, and herbal supplements.**

Amphetamine sulfate tablets 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 amphetamine sulfate tablets.

Your doctor will decide whether amphetamine sulfate tablets 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 amphetamine sulfate tablets without talking to your doctor first.**

**How should I take amphetamine sulfate tablets?**

- Take amphetamine sulfate tablets 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.
- Amphetamine sulfate tablets may cause problems sleeping if taken late at night.
- Amphetamine sulfate tablets can be taken with or without food.
- From time to time, your doctor may stop amphetamine sulfate tablets treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking amphetamine sulfate tablets.
- Children should have their height and weight checked often while taking amphetamine sulfate tablets. Amphetamine sulfate tablets treatment may be stopped if a problem is found during these check-ups.
- If you or your child takes too much amphetamine sulfate tablets, call your doctor right away, or go to the nearest hospital emergency room.

**What should I avoid while taking amphetamine sulfate tablets?**

Do not drive, operate machinery, or do other dangerous activities until you know how amphetamine sulfate tablets affects you.

**What are possible side effects of amphetamine sulfate tablets?**

**Amphetamine sulfate tablets may cause serious side effects, including:**

See "**What is the most important information I should know about amphetamine sulfate tablets?**" 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 amphetamine sulfate tablets 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 amphetamine sulfate tablets 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 amphetamine sulfate tablets. For more information ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to Granules Pharmaceuticals Inc. at 1-877-770-3183 or FDA at 1-800-FDA-1088.

**How should I store amphetamine sulfate tablets?**

- Store amphetamine sulfate tablets at room temperature between 20°C to 25°C (68°F to 77°F).
- Keep amphetamine sulfate tablets and all medicines out of the reach of children.

### **General information about the safe and effective use of amphetamine sulfate tablets.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use amphetamine sulfate tablets for a condition for which it was not prescribed. Do not give amphetamine sulfate tablets 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 amphetamine sulfate. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about amphetamine sulfate that was written for healthcare professionals.

For more information about amphetamine sulfate, please contact Granules Pharmaceuticals Inc. at 1-877-770-3183.

### **What are the ingredients in amphetamine sulfate tablets?**

**Active Ingredient:** amphetamine sulfate, USP

**Inactive Ingredients:** crospovidone, silicified microcrystalline cellulose, and stearic acid. The 10 mg tablets also contain FD&C Blue #1 aluminum lake.

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

Dispense with medication guide is also available at:  
<http://www.granulesindia.com/U.S.ProductCatalog.php>

Manufactured by:

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Rev. 12/2021