

MEDICATION GUIDE

DEXTROAMPHETAMINE SULFATE (DEX-troe-am-FET-a-meen SUL-fate) ORAL SOLUTION

Rx Only

Please read the Medication Guide that comes with Dextroamphetamine Sulfate Oral Solution before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your or your child's treatment with Dextroamphetamine Sulfate Oral Solution.

What is the most important information I should know about Dextroamphetamine Sulfate Oral Solution?

The following have been reported with use of Dextroamphetamine Sulfate Oral Solution and other stimulant medicines.

1. Heart-related problems:

- **sudden death in patients 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 have 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 Dextroamphetamine Sulfate Oral Solution.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with Dextroamphetamine Sulfate Oral Solution.

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 Dextroamphetamine Sulfate Oral Solution.

2. Mental (Psychiatric) problems:

All Patients

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

Children and Teenagers

- **new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or 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 Dextroamphetamine Sulfate Oral Solution, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What is Dextroamphetamine Sulfate Oral Solution?

Dextroamphetamine Sulfate Oral Solution is a central nervous system stimulant prescription medicine. **It is used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD).** Dextroamphetamine Sulfate Oral Solution may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Dextroamphetamine Sulfate Oral Solution should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Dextroamphetamine Sulfate Oral Solution is also used in the treatment of a sleep disorder called narcolepsy.

Dextroamphetamine Sulfate Oral Solution is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Dextroamphetamine Sulfate Oral Solution in a safe place to prevent misuse and abuse. Selling or giving away Dextroamphetamine Sulfate Oral Solution may harm others, and is against the law.

Tell your doctor if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take Dextroamphetamine Sulfate Oral Solution?

Dextroamphetamine Sulfate Oral Solution should not be taken if you or your child:

- have heart disease or hardening of the arteries
- have moderate to severe high blood pressure
- have hyperthyroidism
- have an eye problem called glaucoma
- are very anxious, tense, or agitated
- have a history of drug abuse
- are taking or have taken within the past 14 days an antidepressant medicine called a monoamine oxidase inhibitor or MAOI
- is sensitive to, allergic to, or had a reaction to other stimulant medicines

Dextroamphetamine Sulfate Oral Solution is not recommended for use in children less than 3 years old.

Dextroamphetamine Sulfate Oral Solution may not be right for you or your child.

Before starting Dextroamphetamine Sulfate Oral Solution tell your or your child's doctor about all health conditions (or a family history of) including:

- 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)

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breastfeeding.

Can Dextroamphetamine Sulfate Oral Solution be taken with other medicines?

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

Dextroamphetamine Sulfate Oral Solution 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 Dextroamphetamine Sulfate Oral Solution.

Your doctor will decide whether Dextroamphetamine Sulfate Oral Solution can be taken with other medicines.

Especially tell your doctor if you or your child takes:

- antidepressant medicines including MAOIs
- antacids
- blood pressure medicines
- seizure medicines

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.

Do not start any new medicine while taking Dextroamphetamine Sulfate Oral Solution without talking to your doctor first.**How should Dextroamphetamine Sulfate Oral Solution be taken?**

- **Take Dextroamphetamine Sulfate Oral Solution exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- Dextroamphetamine Sulfate Oral Solution is usually taken two to three times a day. The first dose is usually taken in the morning. One or two more doses may be taken during the day, 4 to 6 hours apart.
- From time to time, your doctor may stop Dextroamphetamine Sulfate Oral Solution treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking Dextroamphetamine Sulfate Oral Solution. Children should have their height and weight checked often while taking Dextroamphetamine Sulfate Oral Solution. Dextroamphetamine Sulfate Oral Solution treatment may be stopped if a problem is found during these check-ups.
- **If you or your child takes too much Dextroamphetamine Sulfate Oral Solution or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of Dextroamphetamine Sulfate Oral Solution?

See “**What is the most important information I should know about Dextroamphetamine Sulfate Oral Solution?**” for information on reported heart and mental problems.

Other serious side effects include:

- slowing of growth (height and weight) in children
- seizures, mainly in patients with a history of seizures
- eyesight changes or blurred vision

Common side effects include:

- fast heart beat
- stomach upset
- headache
- tremors
- dry mouth
- dizziness
- trouble sleeping
- decreased appetite
- weight loss

Dextroamphetamine Sulfate Oral Solution may affect you or your child’s ability to drive or do other dangerous activities.

Talk to your doctor if you or your child has side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Dextroamphetamine Sulfate Oral Solution?

- Store Dextroamphetamine Sulfate Oral Solution in a safe place controlled room temperature, 68° to 77°F (20° to 25°C); Protect from light.
- Keep Dextroamphetamine Sulfate Oral Solution and all medicines out of the reach of children.

General information about Dextroamphetamine Sulfate Oral Solution

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

What are the ingredients in Dextroamphetamine Sulfate Oral Solution?

Active Ingredient: dextroamphetamine sulfate
Inactive Ingredients: anhydrous citric acid, benzoic acid, bubble gum flavor, purified water, sodium citrate anhydrous, sodium saccharin, and sorbitol solution.

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

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