

MEDICATION GUIDE [Ⓜ]
DEXTROAMPHETAMINE SULFATE
EXTENDED-RELEASE CAPSULES

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Read the Medication Guide that comes with Dextroamphetamine Sulfate Extended-Release Capsules 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 you or your child's treatment with Dextroamphetamine Sulfate Extended-Release Capsules.

What is the most important information I should know about Dextroamphetamine Sulfate Extended-Release Capsules?

The following have been reported with use of Dextroamphetamine Sulfate Extended-Release Capsules 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 Extended-Release Capsules. Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with Dextroamphetamine Sulfate Extended-Release Capsules.

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 Dextroamphetamine Sulfate Extended-Release Capsules.

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 Extended-Release Capsules, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What are Dextroamphetamine Sulfate Extended-Release Capsules?

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

Dextroamphetamine Sulfate Extended-Release Capsules should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Dextroamphetamine Sulfate Extended-Release Capsules are also used in the treatment of a sleep disorder called narcolepsy.

Dextroamphetamine Sulfate is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Dextroamphetamine Sulfate Extended-Release Capsules in a safe place to prevent misuse and abuse. Selling or giving away Dextroamphetamine Sulfate Extended-Release Capsules 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 Extended-Release Capsules?

Dextroamphetamine Sulfate Extended-Release Capsules 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 anti-depression medicine called a monoamine oxidase inhibitor or MAOI.
- are sensitive to, allergic to, or had a reaction to other stimulant medicines

Dextroamphetamine Sulfate Extended-Release Capsules are not recommended for use in children less than 3 years old.

Dextroamphetamine Sulfate Extended-Release Capsules may not be right for you or your child. Before starting Dextroamphetamine Sulfate Extended-Release Capsules 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 are pregnant, planning to become pregnant, or breastfeeding.

Can Dextroamphetamine Sulfate Extended-Release Capsules 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 Extended-Release Capsules 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 Extended-Release Capsules.

Your doctor will decide whether Dextroamphetamine Sulfate Extended-Release Capsules can be taken with other medicines.

Especially tell your doctor if you or your child take:

- anti-depression medicines including MAOIs
- blood pressure medicines
- antacids
- seizure medicines

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

Do not start any new medicine while taking Dextroamphetamine Sulfate Extended-Release Capsules without talking to your doctor first.

How should Dextroamphetamine Sulfate Extended-Release Capsules be taken?

- **Take Dextroamphetamine Sulfate Extended-Release Capsules exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- Dextroamphetamine Sulfate Extended-Release Capsules are usually taken once a day in the morning. Dextroamphetamine Sulfate Extended-Release Capsules is an extended release capsule. It releases medicine into your body throughout the day.
- From time to time, your doctor may stop Dextroamphetamine Sulfate Extended-Release Capsule 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 Extended-Release Capsules. Children should have their height and weight checked often while taking Dextroamphetamine Sulfate Extended-Release Capsules. Dextroamphetamine Sulfate Extended-Release Capsule treatment may be stopped if a problem is found during these check-ups.
- **If you or your child take too much Dextroamphetamine Sulfate Extended-Release Capsules or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of Dextroamphetamine Sulfate Extended-Release Capsules?

See “**What is the most important information I should know about Dextroamphetamine Sulfate Extended-Release Capsules?**” 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
- headache
- stomach upset
- decreased appetite
- trouble sleeping
- weight loss
- tremors
- dizziness
- dry mouth

Dextroamphetamine Sulfate Extended-Release Capsules may affect your or your child’s ability to drive or do other dangerous activities.

Talk to your doctor if you or your child have 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.

How should I store Dextroamphetamine Sulfate Extended-Release Capsules?

- Store Dextroamphetamine Sulfate Extended-Release Capsules in a safe place at room temperature, 20° to 25°C (68° to 77°F).
- **Keep Dextroamphetamine Sulfate Extended-Release Capsules and all medicines out of the reach of children.**

General information about Dextroamphetamine Sulfate Extended-Release Capsules

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Dextroamphetamine Sulfate Extended-Release Capsules for a condition for which they were not prescribed. Do not give Dextroamphetamine Sulfate Extended-Release Capsules 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 Extended-Release Capsules. If you would like more information, talk with your doctor.

You can ask your doctor or pharmacist for information about Dextroamphetamine Sulfate Extended-Release Capsules that was written for healthcare professionals.

What are the ingredients in Dextroamphetamine Sulfate Extended-Release Capsules?

Active Ingredient: dextroamphetamine sulfate

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

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