

MEDICATION GUIDE

ProCentra® (dextroamphetamine sulfate) Oral Solution, 5 mg/5 mL CII

Please read the Medication Guide that comes with ProCentra® (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 ProCentra®.

What is the most important information I should know about ProCentra®?

The following have been reported with use of ProCentra® 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 ProCentra®.

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

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 ProCentra®.

All Patients (Psychiatric) problems

- 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 ProCentra®, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What is ProCentra®?

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

ProCentra® should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

ProCentra® is also used in the treatment of a sleep disorder called narcolepsy.

ProCentra® (dextroamphetamine sulfate) Oral Solution is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep ProCentra® in a safe place to prevent misuse and abuse. Selling or giving away ProCentra® 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 ProCentra®?

ProCentra® 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

ProCentra® is not recommended for use in children less than 3 years old.

ProCentra® may not be right for you or your child.

Before starting ProCentra® 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 ProCentra® 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.

ProCentra® 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 ProCentra®.

Your doctor will decide whether ProCentra® 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 ProCentra® without talking to your doctor first.

How should ProCentra® be taken?

- **Take ProCentra® exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- ProCentra® 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 ProCentra® treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking ProCentra®. Children should have their height and weight checked often while taking ProCentra®. ProCentra® treatment may be stopped if a problem is found during these check-ups.
- **If you or your child takes too much ProCentra® or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of ProCentra®?

See “**What is the most important information I should know about ProCentra®?**” 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

ProCentra® 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 ProCentra®?

- Store ProCentra® in a safe place at room temperature, 68° to 77°F (20° to 25°C). Protect from light.
- Keep ProCentra® and all medicines out of the reach of children.

General information about ProCentra®

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ProCentra® for a condition for which it was not prescribed. Do not give ProCentra® 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 ProCentra®. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ProCentra® that was written for healthcare professionals. For more information about ProCentra®, please contact FSC Laboratories, Inc. at 1-704-941-2500.

What are the ingredients in ProCentra®?

Active Ingredient: dextroamphetamine sulfate

Inactive Ingredients: benzoic acid, citric acid anhydrous, purified water, sodium citrate hydrous, sodium saccharin, sorbitol solution, and artificial bubble gum flavor.

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

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