**INDICATIONS AND USAGE**

**Children with Hyperactivity:** As an integral part of a total treatment program that may include education, psychological, and social services, ProCentra® (dextroamphetamine sulfate) Oral Solution is indicated in the management of the symptoms of hyperactivity associated with Attention Deficit Disorder with Hyperactivity. The diagnosis of this disorder should not be made with certainty for children or adolescents with similarly severe behavior problems who do not have evidence of hyperactivity. It should be particularly emphasized that the administration of stimulant drugs is not recommended for children and adolescents with primarily behavioral problems without any evidence of associated motor hyperactivity.

**Adults:**

The diagnosis of adult Attention Deficit Disorder with Hyperactivity should be based on a comprehensive evaluation that includes a careful history and physical examination. A test of the release of norepinephrine and other monoamines from adrenergic nerve endings; this can change the concentration of the ionized species of the amphetamine molecule, thereby increasing urinary excretion. Second, adult patients are more likely than children to experience serious cardiovascular complications, such as myocardial infarction or arrhythmias, associated with the use of stimulants. Third, because of the greater size of the adult population, the statistical significance of any drug-related adverse experiences reported in the elderly may be more likely to emerge than is the case with small children.

**Over 2000 Children and Adolescents**: The diagnosis of hyperactivity disorder should be based on the assessment of a comprehensive evaluation of the patient and, as appropriate, the family, school, and other significant social and community group members.

**Over 2000 Adults**: The diagnosis of hyperactivity disorder should be based on clinical judgment that should include a comprehensive evaluation of the patient and, as appropriate, the family, school, and other significant social and community group members. In adults, the diagnosis of hyperactivity disorder should be considered when there is evidence of persistent patterns of inattention, hyperactivity, and impulsivity that cause clinically significant impairment in social, occupational, or other important areas of functioning. In addition, the clinician should also consider whether there is a co-morbid medical, psychiatric, or neurological condition that might be active in mediating the symptoms of hyperactivity disorder.

**CONTRAINDICATIONS**

**Children:**

- **Menstrual Disorders:** The administration of octopamine may be accompanied by a withdrawal effect (e.g., rebound) after discontinuation of treatment with stimulant drugs.

- **Drug Overdosage:** In cases of propoxyphene overdosage, amphetamines CNS stimulation is not observed. However, patients should be monitored for the appearance of, or worsening of, aggressive behavior or hostility.

- **Psychotic illnesses and mania:** Amphetamines can be used to treat narcoleptics or other patients with symptoms of hyperactivity disorder.

- **Seizures:** Amphetamines can be useful in the management of the symptoms of hyperactivity associated with Attention Deficit Disorder with Hyperactivity. This includes the withdrawal of severe behavior problems that are associated with stimulant drug treatment.

- **Weight Loss:** Weight loss can be a characteristic of treatment with stimulant drugs. This includes the withdrawal of severe behavior problems that are associated with stimulant drug treatment.

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**ADVERSE REACTIONS**

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MEDICATION GUIDE

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

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®.

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

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.

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 younger 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
• Seizures or have had an abnormal brain wave test (EEG)
• Circulation problems in fingers and toes

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 take:
• Anti-depression medicines including MAOIs
• Blood pressure medicines
• 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 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 or 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 treatment with ProCentra® 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 weight and height checked often while taking ProCentra®. Treatment with ProCentra® may be stopped if a problem is found during these check-ups.
• If you or your child take 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
• Tremors
• Trouble sleeping
• Stomach upset
• Dry mouth

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 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. 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 to prevent misuse or abuse. Selling or giving away ProCentra® may harm others, and is against the law.
• 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 Independence Pharmaceuticals, LLC at 1-855-325-1928.

What are the ingredients in ProCentra®?
Active Ingredient: dextroamphetamine sulfate

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

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

Distributed By:
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