

**MEDICATION GUIDE**  
**ProCentra® (dextroamphetamine sulfate) Oral Solution, CII**  
**(pro-SEN-tra)**

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

**ProCentra may cause serious side effects, including:**

- **Abuse, misuse, and addiction.** ProCentra has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of ProCentra, other amphetamine containing medicines, and methylphenidate containing medicines, can lead to overdose and death. The risk of overdose and death is increased with higher doses of ProCentra or when it is used in ways that are not approved, such as snorting or injection.
  - Your healthcare provider should check you or your child's risk for abuse, misuse, and addiction before starting treatment with ProCentra and will monitor you or your child during treatment.
  - ProCentra may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
  - Do not give ProCentra to anyone else. See **“What is ProCentra?”** for more information.
  - Keep ProCentra in a safe place and properly dispose of any unused medicine. See **“How do I store ProCentra?”** for more information.
  - Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.
- **Risks for people with serious heart disease:** Sudden death has happened in people who have heart defects or other serious heart disease.

Your healthcare provider should check you or your child carefully for heart problems before starting treatment with ProCentra. Tell your healthcare provider if you or your child have any heart problems, heart disease, or heart defects.

**Call your healthcare provider right away or go to the nearest hospital emergency room right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with ProCentra.**

- **Increased blood pressure and heart rate.**  
Your healthcare provider should check you or your child's blood pressure and heart rate regularly during treatment with ProCentra.
- **Mental (psychiatric) problems, including:**
  - new or worse behavior or thought problems
  - new or worse bipolar illness
  - new psychotic symptoms (such as hearing voices, or seeing or believing things that are not real) or new manic symptoms

Tell your healthcare provider about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

**Call your healthcare provider right away if you or your child have any new or worsening mental symptoms or problems during treatment with ProCentra, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.**

**What is ProCentra?**

ProCentra is a central nervous system (CNS) stimulant prescription medicine used for the treatment of:

- a sleep disorder called narcolepsy.
- Attention-Deficit Hyperactivity Disorder (ADHD) in children 3 to 16 years of age. ProCentra may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.

It is not known if ProCentra is safe and effective in children under 3 years of age.

**ProCentra is a federally controlled substance (CII) because it contains dextroamphetamine**

**that can be a target for people who abuse prescription medicines or street drugs.** Keep ProCentra in a safe place to protect it from theft. Never give your ProCentra to anyone else because it may cause death or harm them. Selling or giving away ProCentra may harm others and is against the law.

**Do not take ProCentra if you or your child:**

- are allergic to amphetamine products or any of the ingredients in ProCentra. See the end of this Medication Guide for a complete list of ingredients in ProCentra.
- are taking or have taken within the past 14 days, a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI), including the antibiotic linezolid or the intravenous medicine methylene blue.

**Before taking ProCentra, tell your healthcare provider about all of your or your child's medical conditions, including if you or your child:**

- have heart problems, heart disease, heart defects, or high blood pressure
- have mental problems including psychosis, mania, bipolar illness, or depression, or have a family history of suicide, bipolar illness, or depression
- have seizures or have had an abnormal brain wave test (EEG)
- have circulation problems in fingers and toes
- have or had repeated movements or sounds (tics) or Tourette's syndrome, or have a family history of tics or Tourette's syndrome
- are pregnant or plan to become pregnant. It is not known if ProCentra will harm the unborn baby. Tell your healthcare provider if you or your child become pregnant during treatment with ProCentra.
- are breastfeeding or plan to breastfeed. ProCentra passes into breast milk. You or your child should not breastfeed during treatment with ProCentra. Talk to your healthcare provider about the best way to feed the baby during treatment with ProCentra.

**Tell your healthcare provider about all of the medicines that you or your child take,** including prescription and over-the-counter 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 changed during treatment with ProCentra. Your healthcare provider will decide if ProCentra can be taken with other medicines.

**Especially tell your healthcare provider if you or your child take:**

- selective serotonin reuptake inhibitors (SSRIs)
- medicines used to treat migraine headaches called triptans
- lithium
- tramadol
- buspirone
- serotonin norepinephrine reuptake inhibitors (SNRIs)
- tricyclic antidepressants
- fentanyl
- tryptophan
- St. John's Wort

Know the medicines that you or your child take. Keep a list of your or your child's medicines with you to show your healthcare provider and pharmacist when you or your child get a new medicine. **Do not start any new medicine during treatment with ProCentra without talking to your healthcare provider first.**

**How should ProCentra be taken?**

- Take ProCentra exactly as prescribed by your or your child's healthcare provider.
- Your healthcare provider may change the dose if needed.
- 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.

If you or your child take too much ProCentra, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

**What should I avoid while taking ProCentra?**

Do not drive, operate heavy machinery, or do other potentially dangerous activities until you know how ProCentra affects you.

**What are possible side effects of ProCentra?**

**ProCentra may cause serious side effects, including:**

- See **"What is the most important information I should know about ProCentra?"**
- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with ProCentra. Your healthcare provider may stop your child's ProCentra treatment if they are not growing or gaining weight as expected.
- **Seizures.** Your healthcare provider may stop treatment with ProCentra if you or your child have a

seizure.

• **Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud’s phenomenon). Signs and symptoms may include:**

- fingers or toes may feel numb, cool, painful
- fingers or toes may change color from pale, to blue, to red

Tell your healthcare provider if you or your child have numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.

**Call your healthcare provider right away if you or your child have any signs of unexplained wounds appearing on fingers or toes during treatment with ProCentra.**

- **New or worsening tics or worsening Tourette’s syndrome.** Tell your healthcare provider if you or your child get any new or worsening tics or worsening Tourette’s syndrome during treatment with ProCentra.
- **Serotonin syndrome.** This problem may happen when ProCentra is taken with certain other medicines and may be life-threatening. Stop taking ProCentra and call your healthcare provider or go to the nearest hospital emergency room right away if you or your child develop any of the following signs and symptoms of serotonin syndrome:

- agitation
- fast heartbeat
- flushing
- seizures
- coma
- sweating
- loss of coordination
- confusion
- dizziness
- tremors, stiff muscles, or muscle twitching
- seeing or hearing things that are not real (hallucination)
- changes in blood pressure
- high body temperature (hyperthermia)
- nausea, vomiting, diarrhea

**The most common side effects of ProCentra include:**

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

These are not all of the possible side effects of ProCentra.

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

**How do I store ProCentra?**

- Store ProCentra at room temperature between 68° to 77°F (20° to 25°C).
- Store ProCentra in a safe place, like a locked cabinet. Protect from light.
- Dispose of remaining, unused, or expired ProCentra by a medicine take back program at a U.S. Drug Enforcement Administration (DEA) authorized collection site. If no take back program or DEA authorized collector is available, mix ProCentra with an undesirable, nontoxic substance such as dirt, cat litter, or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container such as a sealed plastic bag and throw away ProCentra in the household trash. Visit [www.fda.gov/drugdisposal](http://www.fda.gov/drugdisposal) for additional information on disposal of unused medicines.

**Keep ProCentra and all medicines out of the reach of children.**

**General information about the safe and effective use of 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 symptoms that you or your child have. It may harm them and it is against the law. You can ask your healthcare provider or pharmacist for information about ProCentra that is written for healthcare professionals.

**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 bubblegum flavor.

Manufactured for:

Independence Pharmaceuticals, LLC

Newport, KY 41071 USA

Distributed by:

Prasco, LLC

Mason, OH 45040 USA

Code 983E00-P

For more information about ProCentra, please contact Prasco, LLC at 1-866-525-0688.

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

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