PROCENTRA® C II
(dextroamphetamine sulfate) ORAL SOLUTION

FOR NARCOLEPSY

Navigating the unique treatment needs of patients living with narcolepsy

The short-acting liquid amphetamine to treat daytime symptoms when they need it most

Immediate Release Drug Delivery
Provides daytime symptom control when needed during peak activity

Liquid Formulation
An option for those who have difficulty swallowing medication

Flexible Dosing
Proven effective in daily dosing intervals of 4-6 hours

Daytime Dosing
Take only as prescribed during wakeful hours — suggested first dose in the morning

Patients should take ProCentra exactly as prescribed.
See Prescribing Information for dosage and administration information.

IMPORTANT SAFETY INFORMATION

ProCentra® (dextroamphetamine sulfate) Oral Solution, CII

INDICATIONS AND USAGE

ProCentra® (dextroamphetamine sulfate) is a prescription medicine for the treatment of Narcolepsy. ProCentra is also indicated as a treatment for Attention Deficit Disorder with Hyperactivity (ADHD) in pediatric patients ages 3 to 16 years as an integral part of a total treatment program for ADHD that may include counseling or other remedial measures for a stabilizing effect.

IMPORTANT SAFETY INFORMATION

WARNING: ABUSE, MISUSE, AND ADDICTION
Dextroamphetamine sulfate has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including dextroamphetamine sulfate, can result in overdose and death. This risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

Before prescribing dextroamphetamine sulfate, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout dextroamphetamine sulfate treatment, reassess each patient's risk of, and frequently monitor for signs and symptoms of, abuse, misuse, and addiction.

IMPORTANT SAFETY INFORMATION (cont.)

CONTRAINDICATIONS

- Known hypersensitivity to amphetamine products.
- During or within 14 days following the administration of monoamine oxidase inhibitors (hypertensive crisis may result).

WARNINGS AND PRECAUTIONS

- **Abuse, Misuse, and Addiction: See boxed warning above.**
- **Risks to Patients with Serious Cardiac Disease:** Sudden death has been reported in patients with structural cardiac abnormalities or other serious cardiac disease who are treated with CNS stimulants at the recommended ADHD dosages. Avoid ProCentra use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease. Instruct patients to contact a healthcare provider immediately if they develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease.
- **Increased Blood Pressure and Heart Rate:** CNS stimulants cause an increase in blood pressure (mean increase about 2 to 4 mm Hg) and heart rate (mean increase about 3 to 6 bpm). Monitor all patients for potential tachycardia and hypertension.
- **Psychiatric Adverse Reactions:** *Exacerbation of Pre-Existing Psychosis:* CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder. *Induction of a Manic Episode in Patients with Bipolar Disorder:* CNS stimulants may induce a manic or mixed episode in patients. Prior to initiating treatment, screen patients for risk factors for developing a manic episode (e.g., comorbid or history of depressive symptoms or a family history of suicide, bipolar disorder, or depression). *New Psychotic or Manic Symptoms:* CNS stimulants, at recommended doses, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without a prior history of psychotic illness or mania. If such symptoms occur, consider discontinuing dextroamphetamine sulfate.
- **Long-Term Suppression of Growth in Pediatric Patients:** CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients, including dextroamphetamine sulfate. Closely monitor growth (weight and height) in ProCentra-treated pediatric patients treated with CNS stimulants. Pediatric patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted.
- **Seizures:** There is some clinical evidence that stimulants may lower the convulsive threshold in patients with prior history of seizures, or prior EEG abnormalities in absence of seizures, and, very rarely, in patients without a history of seizures and no prior EEG evidence of seizures. In the presence of seizures, the drug should be discontinued.
- **Peripheral Vasculopathy, Including Raynaud's Phenomenon:** Stimulants, including dextroamphetamine sulfate oral solution, used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, very rare sequelae include digital ulcerations and/or soft tissue breakdown. Signs and symptoms generally improved after dosage reduction or discontinuation of the CNS stimulant. Careful observation for digital changes is necessary during ProCentra-treatment. Patients should call their physician immediately with any signs of unexplained wounds appearing on fingers or toes while taking ProCentra. Further evaluation may be required, including rheumatology referral.
- **Serotonin Syndrome:** Serotonin syndrome, a potentially life-threatening reaction, may occur when amphetamines are used with other drugs that affect the serotonergic neurotransmitter systems such as monoamine oxidase inhibitors (MAOI), selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort and cytochrome P450 (CYP2D6) inhibitors. Concomitant use of ProCentra with MAOI drugs is contraindicated. Discontinue treatment with ProCentra and any concomitant serotonergic agents immediately if serotonin syndrome symptoms occur (e.g., mental status changes, autonomic instability, neuromuscular symptoms, seizures, and/or gastrointerstinal symptoms), and initiate supportive symptomatic treatment. If concomitant use of ProCentra with other serotonergic drugs or CYP2D6 inhibitors is clinically warranted, initiate ProCentra with lower doses, monitor patients for the emergence of serotonin syndrome during drug initiation or titration, and inform patients of the increased risk for serotonin syndrome.
- **Motor and Verbal Tics, and Worsening of Tourette's Syndrome:** CNS stimulants, including dextroamphetamine sulfate, have been associated with the onset or exacerbation of motor and verbal tics and worsening of Tourette's syndrome. Assess the family history and clinically evaluate patients for tics or Tourette's syndrome before initiating dextroamphetamine sulfate. Regularly monitor patients for the emergence or worsening of tics or Tourette's syndrome, and discontinue treatment if clinically appropriate.

ADVERSE REACTIONS

- **Cardiovascular:** Palpitations, tachycardia, elevation of blood pressure. There have been isolated reports of cardiomyopathy associated with chronic amphetamine use.
- **Central Nervous System:** Psychotic episodes at recommended doses (rare), overstimulation, restlessness, dizziness, insomnia, euphoria, dyskinesia, dysphoria, tremor, headache, exacerbation of motor and verbal tics and Tourette's syndrome.
- **Gastrointestinal:** Dryness of the mouth, unpleasant taste, diarrhea, constipation, intestinal ischemia and other gastrointestinal disturbances. Anorexia and weight loss may occur as undesirable effects.
- **Allergic:** Urticaria.
- **Endocrine:** Impotence, changes in libido.
- **Musculoskeletal:** Rhabdomyolysis.

IMPORTANT SAFETY INFORMATION (cont.)

USE IN SPECIFIC POPULATIONS

- **Pregnancy Category C:** Animal reproduction studies have shown an adverse effect on the fetus. While there are no adequate and well-controlled studies in pregnant women, there has been one report of severe congenital bony deformity, tracheoesophageal fistula, and anal atresia (VATER association) in a baby born to a woman who took dextroamphetamine sulfate with lovastatin during the first trimester of pregnancy. Dextroamphetamine sulfate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers dependent on amphetamines have an increased risk of premature delivery and low birth weight. Also, these infants may experience symptoms of withdrawal as demonstrated by dysphoria, including agitation, and significant lassitude.
- **Nursing Mothers:** Amphetamines are excreted in human milk. Mothers taking amphetamines should be advised to refrain from nursing.
- **Pediatric Use:** Long-term effects of amphetamines in pediatric patients have not been well established. Amphetamines are not recommended for use in pediatric patients under 3 years of age with ADHD. Clinical experience suggests that in psychotic children, administration of amphetamines may exacerbate symptoms of behavior disturbance and thought disorder. Drug treatment is not indicated in all cases of ADHD and should be considered only in light of the complete history and evaluation of the child.

DRUG ABUSE AND DEPENDENCE

- Dextroamphetamine sulfate is a Schedule II controlled substance.
- Abuse – Dextroamphetamine sulfate has a high potential for abuse, misuse, and substance use disorder, including addiction. Dextroamphetamine sulfate can be diverted for non-medical use into illicit channels or distribution. Misuse and abuse of amphetamines may cause increased heart rate, respiratory rate, or blood pressure; sweating; dilated pupils; hyperactivity; restlessness; insomnia; decreased appetite; loss of coordination; tremors; flushed skin; vomiting; abdominal pain; anxiety; psychosis; hostility; aggression; and/or suicidal or homicidal ideation. Misuse and abuse of CNS stimulants, including dextroamphetamine sulfate, can result in overdose and death. This risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.
- Physical Dependence - Dextroamphetamine sulfate may produce physical dependence, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction, including dysphoric mood; depression; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation.
- Tolerance - Dextroamphetamine sulfate may produce tolerance (i.e., a higher dose of a drug is required to produce the same effect that was once obtained at a lower dose).

OVERDOSE

Clinical Effects of Overdose

Overdose of CNS stimulants is characterized by the following sympathomimetic effects:

- Cardiovascular effects including tachyarrhythmias, and hypertension or hypotension. Vasospasm, myocardial infarction, or aortic dissection may precipitate sudden cardiac death. Takotsubo cardiomyopathy may develop.
- CNS effects including psychomotor agitation, confusion, and hallucinations. Serotonin syndrome, seizures, cerebral vascular accidents, and coma may occur.
- Life-threatening hyperthermia (temperatures greater than 104°F) and rhabdomyolysis may develop.

Overdose Management

Consider the possibility of multiple drug ingestion. D-amphetamine is not dialyzable.

Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdose management recommendations.

This is not a complete summary of safety information. For additional safety Information, see **Full Prescribing Information** and **Medication Guide**.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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