

**MEDICATION GUIDE**  
**Lisdexamfetamine Dimesylate Capsules, CII**  
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Medication Guide available at <https://www.apotex.com/products/us/mg.asp>

**What is the most important information I should know about lisdexamfetamine dimesylate capsules?**

**Lisdexamfetamine dimesylate capsules may cause serious side effects, including:**

- **Abuse and dependence.** Lisdexamfetamine dimesylate capsules, other amphetamine containing medicines, and methylphenidate have a high chance for abuse and may cause physical and psychological dependence. Your healthcare provider should check you or your child for signs of abuse and dependence before and during treatment with lisdexamfetamine dimesylate capsules.
  - Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.
  - Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.

- **Heart-related problems including:**

- sudden death, stroke, and heart attack in adults
- sudden death in children who have heart problems or heart defects
- increased blood pressure and heart rate

Your healthcare provider should check you or your child carefully for heart problems before starting treatment with lisdexamfetamine dimesylate capsules. Tell your healthcare provider if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your healthcare provider should check your or your child's blood pressure and heart rate regularly during treatment with lisdexamfetamine dimesylate capsules.

**Call your healthcare provider 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 lisdexamfetamine dimesylate capsules.**

- **Mental (psychiatric) problems, including:**

- new or worse behavior and 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 lisdexamfetamine dimesylate capsules, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.**

**What are lisdexamfetamine dimesylate capsules?**

Lisdexamfetamine dimesylate capsules are a central nervous system (CNS) stimulant prescription medicine used for the treatment of:

- Attention Deficit Hyperactivity Disorder (ADHD) in adults and children 6 years of age and older. Lisdexamfetamine dimesylate capsules may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.
- Moderate to severe binge eating disorder (BED) in adults. Lisdexamfetamine dimesylate capsules may help reduce the number of binge eating days in people with BED.

**Lisdexamfetamine dimesylate capsules are not for use in children under 6 years of age with ADHD.**

Lisdexamfetamine dimesylate capsules are not for weight loss. It is not known if lisdexamfetamine dimesylate capsules are safe and effective for the treatment of obesity. It is not known if lisdexamfetamine dimesylate capsules are safe and effective for use in children with BED.

**Lisdexamfetamine dimesylate capsules are a federally controlled substance (CII) because it contains lisdexamfetamine dimesylate that can be a target for people who abuse prescription medicines or street drugs.** Keep lisdexamfetamine dimesylate capsules in a safe place to protect it from theft. Never give your

lisdexamfetamine dimesylate capsules to anyone else because it may cause death or harm them. Selling or giving away lisdexamfetamine dimesylate capsules may harm others and is against the law.

**Do not take lisdexamfetamine dimesylate capsules if you or your child are:**

- allergic to amphetamine products or any of the ingredients in lisdexamfetamine dimesylate capsules. See the end of this Medication Guide for a complete list of ingredients in lisdexamfetamine dimesylate capsules.
- taking, or have stopped taking in the last 14 days, a medicine called a Monoamine Oxidase Inhibitor (MAOI).
- being treated with the antibiotic linezolid or intravenous methylene blue.

**Before taking lisdexamfetamine dimesylate capsules, tell your healthcare provider about all medical conditions, including if you or your child:**

- have heart problems, 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 circulation problems in fingers and toes
- are pregnant or plan to become pregnant. Lisdexamfetamine dimesylate capsules may harm the unborn baby.
  - There is a pregnancy registry for females who are exposed to lisdexamfetamine dimesylate capsules during pregnancy. The purpose of the registry is to collect information about the health of females exposed to lisdexamfetamine dimesylate capsules and their baby. If you or your child becomes pregnant during treatment with lisdexamfetamine dimesylate capsules, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychostimulants at 1-866-961-2388 or visit online at <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/adhd-medications/>.
- are breastfeeding or plan to breastfeed. Lisdexamfetamine dimesylate passes into breast milk. You should not breastfeed during treatment with lisdexamfetamine dimesylate capsules. Talk to your healthcare provider about the best way to feed the baby during treatment with lisdexamfetamine dimesylate capsules.

**Tell your healthcare provider about all the medicines that you or your child take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Lisdexamfetamine dimesylate capsules can affect the way other medicines work and other medicines may affect how lisdexamfetamine dimesylate capsules works. Taking lisdexamfetamine dimesylate capsules with other medicines can cause serious side effects. Sometimes the doses of other medicines will need to be changed while taking lisdexamfetamine dimesylate capsules.

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

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

Keep a list of all medicines to show your healthcare provider and pharmacist when you get a new medicine. Your healthcare provider will decide if lisdexamfetamine dimesylate capsules can be taken with other medicines.

**Do not start any new medicine during treatment with lisdexamfetamine dimesylate capsules without talking to your healthcare provider first.**

**How should lisdexamfetamine dimesylate capsules be taken?**

- Take lisdexamfetamine dimesylate capsules exactly as prescribed by your healthcare provider.
- Your healthcare provider may change the dose if needed.
- Take lisdexamfetamine dimesylate capsule 1 time each day in the morning with or without food.
- Your healthcare provider may sometimes stop lisdexamfetamine dimesylate capsules treatment for a while to check ADHD or BED symptoms.
- Lisdexamfetamine dimesylate capsules comes in capsules.

### **Taking lisdexamfetamine Dimesylate Capsules:**

- Lisdexamfetamine dimesylate capsules may be swallowed whole.
- If lisdexamfetamine dimesylate capsules cannot be swallowed whole, the capsule may be opened and the entire contents sprinkled onto yogurt, or poured into water or orange juice.
  - Using a spoon, break apart any powder that is stuck together. Stir the lisdexamfetamine dimesylate capsule powder and yogurt, water, or orange juice until they are completely mixed together.
  - Swallow all the yogurt, water, or orange juice mixture right away. **Do not** store the yogurt, water, or orange juice mixture.
  - It is normal to see a filmy coating on the inside of your glass or container after you eat or drink all the lisdexamfetamine dimesylate capsule mixture.

If you or your child take too much lisdexamfetamine dimesylate capsules, call your healthcare provider or poison control center at 1-800-222-1222 or go to the nearest hospital emergency room right away.

### **What should I avoid while taking lisdexamfetamine dimesylate capsules?**

Do not drive, operate machinery, or do other dangerous activities until you know how lisdexamfetamine dimesylate capsules affects you.

### **What are the possible side effects of lisdexamfetamine dimesylate capsules?**

**Lisdexamfetamine dimesylate capsules may cause serious side effects, including:**

- See **“What is the most important information I should know about lisdexamfetamine dimesylate capsules?”**
- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with lisdexamfetamine dimesylate capsules. Lisdexamfetamine dimesylate capsules treatment may be stopped if your child is not growing or gaining weight.
- **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 lisdexamfetamine dimesylate capsules.

- **Serotonin Syndrome.** A potentially life-threatening problem called serotonin syndrome may happen when Lisdexamfetamine dimesylate capsules are taken with certain other medicines. Stop taking lisdexamfetamine dimesylate capsules 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
  - flushing
  - coma
  - loss of coordination
  - dizziness
  - seeing or hearing things that are not real (hallucination)
  - high body temperature (hyperthermia)
  - fast heartbeat
  - seizures
  - sweating
  - confusion
  - tremors, stiff muscles, or muscle twitching
  - changes in blood pressure
  - nausea, vomiting, diarrhea

**The most common side effects of lisdexamfetamine dimesylate capsules in children 6 to 17 years old and adults with ADHD include:**

- loss of appetite (anorexia)
- decreased appetite
- diarrhea
- dry mouth
- anxiety
- weight loss
- dizziness
- irritability

- trouble sleeping
- stomach pain
- nausea
- vomiting

**The most common side effects of lisdexamfetamine dimesylate capsules in adults with BED include:**

- dry mouth
- decreased appetite
- constipation
- anxiety
- trouble sleeping
- increased heart rate
- feeling jittery

These are not all the possible side effects of lisdexamfetamine dimesylate capsules.

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 lisdexamfetamine dimesylate capsules?**

- Store lisdexamfetamine dimesylate capsules in a safe place (like a locked cabinet) and in a tightly closed container at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect lisdexamfetamine dimesylate capsules from light.
- Dispose of remaining, unused, or expired lisdexamfetamine dimesylate capsules by a medicine take-back program at authorized collection sites such as retail pharmacies, hospital or clinic pharmacies, and law enforcement locations. If no take-back program or authorized collector is available, mix lisdexamfetamine dimesylate capsule 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 (discard) lisdexamfetamine dimesylate capsule in the household trash.

**Keep lisdexamfetamine dimesylate capsules and all medicines out of the reach of children.**

**General information about the safe and effective use of lisdexamfetamine dimesylate capsules.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use lisdexamfetamine dimesylate capsules for a condition for which it was not prescribed. Do not give lisdexamfetamine dimesylate capsules to other people, even if they have the same symptoms that you have. It may harm them and it is against the law. You can ask your pharmacist or healthcare provider for information about lisdexamfetamine dimesylate capsules that is written for health professionals.

**What are the ingredients in lisdexamfetamine dimesylate capsules?**

**Active ingredient:** lisdexamfetamine dimesylate

**Capsule Inactive ingredients:** colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, and microcrystalline cellulose. The capsule shells contain gelatin, titanium dioxide, and one or more of the following: D&C Red #28 (70 mg), FD&C Blue #1 (40 mg, 50 mg, 60 mg and 70 mg), FD&C Red #3 (10 mg and 30 mg), FD&C Red #40 (70 mg), FD&C Yellow #6 (30 mg and 70 mg), iron oxide black (40 mg), and iron oxide yellow (20 mg and 40 mg). The imprinting ink of the 10 mg capsules contains iron oxide black, potassium hydroxide, propylene glycol, shellac, and strong ammonia solution. The imprinting ink of 20 mg, 30 mg, 40 mg, 50 mg, 60 mg and 70 mg capsules contains ammonium hydroxide, iron oxide black, propylene glycol, and shellac glaze.

**APOTEX INC.**

**LISDEXAMFETAMINE DIMESYLATE CAPSULES**

**10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg**

<b>Manufactured by:</b> Frontida Biopharm, LLC 1100 Orthodox Street Philadelphia, PA 19124 USA	<b>Manufactured</b> Apotex Corp. Weston, Florida USA 33326
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