MEDICATION GUIDE
Lisdexamfetamine Dimesylate
(lis dex″ am fet′ a meen dye mes′ i late)
Capsules, CII

What is the most important information I should know about lisdexamfetamine dimesylate capsules?
Lisdexamfetamine dimesylate capsules may cause serious side effects, including:

- **Abuse, misuse, and addiction.** Lisdexamfetamine dimesylate capsules have a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of lisdexamfetamine dimesylate capsules, 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 lisdexamfetamine dimesylate capsules 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 lisdexamfetamine dimesylate capsules and will monitor you or your child during treatment.
  - Lisdexamfetamine dimesylate capsules may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
  - Do not give lisdexamfetamine dimesylate capsules to anyone else. See "**What are lisdexamfetamine dimesylate capsules?**" for more information.
  - Keep lisdexamfetamine dimesylate capsules in a safe place and properly dispose of any unused medicine. See "**How should I store lisdexamfetamine dimesylate capsules?**" 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 lisdexamfetamine dimesylate capsules. 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 lisdexamfetamine dimesylate capsules.
- **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 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 recommended 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 capsule is 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.

Who should not take lisdexamfetamine dimesylate capsules?

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), including 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 disease, heart defects, or high blood pressure, or have a family history of sudden death or heart problems
- 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
- have kidney problems
- 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. Lisdexamfetamine dimesylate capsules may harm the unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with lisdexamfetamine dimesylate capsules.
- 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 during treatment with lisdexamfetamine dimesylate capsules.

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

- 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.

Your healthcare provider may tell you to stop taking lisdexamfetamine dimesylate capsules for a short time before you get certain imaging tests because lisdexamfetamine dimesylate capsules may impact the results of some tests.

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.
- Taking lisdexamfetamine dimesylate capsules in the afternoon may cause trouble sleeping.
- Lisdexamfetamine dimesylate comes in capsules.

  Taking lisdexamfetamine dimesylate capsules:
  - Swallow lisdexamfetamine dimesylate capsules 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 capsules 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 capsules mixture.

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

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 as expected.
- **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
- **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 lisdexamfetamine dimesylate capsules.

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
- anxiety
- weight loss

- diarrhea
- dry mouth
- trouble sleeping
- stomach pain
- dizziness
- irritability
- 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) at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep the container tightly closed and protect lisdexamfetamine dimesylate capsules from light.
- Dispose of remaining, unused, or expired lisdexamfetamine dimesylate capsules 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 lisdexamfetamine dimesylate capsules 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 lisdexamfetamine dimesylate capsules in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

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 for that is written for health professionals.

What are the ingredients in lisdexamfetamine dimesylate capsules?

Active ingredient: lisdexamfetamine dimesylate

Inactive ingredients: croscarmellose sodium, magnesium stearate and microcrystalline cellulose. The capsule shells contain gelatin, titanium dioxide, FD&C Red #3 (in 10 mg), D&C Yellow #10 (in 20 mg), FD&C Yellow #6 (in 20 mg, 30 mg and 70 mg), FD&C Red #40 (in 30 mg and 70 mg), D&C Red #28 (in 30 mg and 70 mg), black iron oxide (in 40 mg), yellow iron oxide (in 40 mg), and FD&C Blue #1 (in 40 mg, 50 mg, 60 mg and 70 mg). In addition, capsule imprinting ink contains ammonia, black iron oxide, potassium hydroxide, propylene glycol and shellac.

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For more information, please contact Granules Pharmaceuticals Inc., at 1-877-770-3183.

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This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 05/2026