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

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

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

What are lisdexamfetamine dimesylate chewable tablets?

Lisdexamfetamine dimesylate chewable tablets 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 chewable tablets may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.
- Moderate to severe binge eating disorder (BED) in adults. Lisdexamfetamine dimesylate chewable tablets may help reduce the number of binge eating days in people with BED.

Lisdexamfetamine dimesylate chewable tablets are not recommended for use in children under 6 years of age with

ADHD.

Lisdexamfetamine dimesylate chewable tablets are not for weight loss. It is not known if lisdexamfetamine dimesylate chewable tablets are safe and effective for the treatment of obesity.

It is not known if lisdexamfetamine dimesylate chewable tablets are safe and effective for use in children with BED.

Lisdexamfetamine dimesylate chewable tablets 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 chewable tablets in a safe place to protect it from theft. Never give your lisdexamfetamine dimesylate chewable tablets to anyone else because it may cause death or harm them. Selling or giving away lisdexamfetamine dimesylate chewable tablets may harm others and is against the law.

Who should not take lisdexamfetamine dimesylate chewable tablets?

Do not take lisdexamfetamine dimesylate chewable tablets if you or your child are:

- allergic to amphetamine products or any of the ingredients in lisdexamfetamine dimesylate chewable tablets. See the end of this Medication Guide for a complete list of ingredients in lisdexamfetamine dimesylate chewable tablets.
- 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 chewable tablets, 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 chewable tablets may harm the unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with lisdexamfetamine dimesylate chewable tablets.
- are breastfeeding or plan to breastfeed. Lisdexamfetamine dimesylate passes into breast milk. You should not breastfeed during treatment with lisdexamfetamine dimesylate chewable tablets. Talk to your healthcare provider about the best way to feed the baby during treatment with lisdexamfetamine dimesylate chewable tablets.

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 chewable tablets can affect the way other medicines work, and other medicines may affect how lisdexamfetamine dimesylate chewable tablets works. Taking lisdexamfetamine dimesylate chewable tablets with other medicines can cause serious side effects. Sometimes the doses of other medicines will need to be changed during treatment with lisdexamfetamine dimesylate chewable tablets.

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 chewable tablets can be taken with other medicines.

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

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

of some tests.

How should lisdexamfetamine dimesylate chewable tablets be taken?

- Take lisdexamfetamine dimesylate chewable tablets exactly as prescribed by your healthcare provider.
- Your healthcare provider may change the dose if needed.
- Take lisdexamfetamine dimesylate chewable tablets 1 time each day in the morning with or without food.
- Taking lisdexamfetamine dimesylate chewable tablets in the afternoon may cause trouble sleeping.
- Lisdexamfetamine dimesylate chewable tablets comes in chewable tablets.

  Taking lisdexamfetamine dimesylate chewable tablets:
  - Chew lisdexamfetamine dimesylate chewable tablets completely before swallowing.

If you or your child take too much lisdexamfetamine dimesylate chewable tablets, 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 chewable tablets?

Lisdexamfetamine dimesylate chewable tablets may cause serious side effects, including:

- See **"What is the most important information I should know about lisdexamfetamine dimesylate chewable tablets?"**
- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with lisdexamfetamine dimesylate chewable tablets. Lisdexamfetamine dimesylate chewable tablets 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 chewable tablets.
- **Serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome may happen when lisdexamfetamine dimesylate chewable tablets are taken with certain other medicines. Stop taking lisdexamfetamine dimesylate chewable tablets 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 chewable tablets.

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

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

- stomach pain
- vomiting

The most common side effects of lisdexamfetamine dimesylate chewable tablets 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 chewable tablets.
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 chewable tablets?

- Store lisdexamfetamine dimesylate chewable tablets 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 chewable tablets from light.
- Dispose of remaining, unused, or expired lisdexamfetamine dimesylate chewable tablets 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 chewable tablets 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 chewable tablets in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

Keep lisdexamfetamine dimesylate chewable tablets and all medicines out of the reach of children.

General information about the safe and effective use of lisdexamfetamine dimesylate chewable tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use lisdexamfetamine dimesylate chewable tablets for a condition for which it was not prescribed. Do not give lisdexamfetamine dimesylate chewable tablets 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 chewable tablets that is written for health professionals.

What are the ingredients in lisdexamfetamine dimesylate chewable tablets?

Active ingredient: lisdexamfetamine dimesylate

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, guar gum, magnesium stearate, mannitol, microcrystalline cellulose, N-C fresh strawberry flavor and sucralose.

Manufactured by:
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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