

MEDICATION GUIDE
VYVANSE® (Vi' – vans)
(lisdexamfetamine dimesylate)
Capsules and Chewable Tablets, CII

What is the most important information I should know about VYVANSE?

VYVANSE may cause serious side effects, including:

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

What is VYVANSE?

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

VYVANSE is not for use in children under 6 years of age with ADHD.

VYVANSE is not for weight loss. It is not known if VYVANSE is safe and effective for the treatment of obesity.

It is not known if VYVANSE is safe and effective for use in children with BED.

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

Do not take VYVANSE if you or your child are:

- allergic to amphetamine products or any of the ingredients in VYVANSE. See the end of this Medication Guide for a complete list of ingredients in VYVANSE.
- 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 VYVANSE, 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
- 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. VYVANSE may harm the unborn baby.
 - There is a pregnancy registry for females who are exposed to VYVANSE during pregnancy. The purpose of the registry is to collect information about the health of females exposed to VYVANSE and their baby. If you or your child becomes pregnant during treatment with VYVANSE, 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. VYVANSE passes into breast milk. You should not breastfeed during treatment with VYVANSE. Talk to your healthcare provider about the best way to feed the baby during treatment with VYVANSE.

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.

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

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 VYVANSE can be taken with other medicines.

Do not start any new medicine during treatment with VYVANSE without talking to your healthcare provider first.

How should VYVANSE be taken?

- Take VYVANSE exactly as prescribed by your healthcare provider.

- Your healthcare provider may change the dose if needed.
- Take VYVANSE 1 time each day in the morning with or without food.
- VYVANSE comes in capsules or chewable tablets.

Taking VYVANSE Capsules:

- VYVANSE capsules may be swallowed whole.
- If VYVANSE 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 VYVANSE 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 VYVANSE mixture.

Taking VYVANSE Chewable Tablets:

- Chew VYVANSE tablets completely before swallowing.

If you or your child take too much VYVANSE, 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 VYVANSE?

VYVANSE may cause serious side effects, including:

- See “**What is the most important information I should know about VYVANSE?**”
- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with VYVANSE. VYVANSE 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 VYVANSE.
- **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 VYVANSE.
- **Serotonin Syndrome.** A potentially life-threatening problem called serotonin syndrome may happen when VYVANSE is taken with certain other medicines. Stop taking VYVANSE 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 VYVANSE in children 6 to 17 years old and adults with ADHD include:

- loss of appetite (anorexia) • anxiety

- decreased appetite
- diarrhea
- dry mouth
- trouble sleeping
- stomach pain
- weight loss
- dizziness
- irritability
- nausea
- vomiting

The most common side effects of VYVANSE 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 VYVANSE.

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 VYVANSE?

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

Keep VYVANSE and all medicines out of the reach of children.

General information about the safe and effective use of VYVANSE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VYVANSE for a condition for which it was not prescribed. Do not give VYVANSE 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 VYVANSE that is written for healthcare professionals.

What are the ingredients in VYVANSE?

Active ingredient: lisdexamfetamine dimesylate

Capsule Inactive ingredients: microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. The capsule shells (imprinted with S489) contain gelatin, titanium dioxide, and one or more of the following: FD&C Red #3, FD&C Yellow #6, FD&C Blue #1, Black Iron Oxide, and Yellow Iron Oxide.

Chewable Tablet Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, guar gum, magnesium stearate, mannitol, microcrystalline cellulose, sucralose, artificial strawberry flavor.

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For more information, go to www.vyvanse.com or call 1-800-828-2088.