

MEDICATION GUIDE
VYVANSE® [*Vi' - vāns*]
(lisdexamfetamine dimesylate) CII
Capsules

Read the Medication Guide that comes with Vyvanse before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your or your child's treatment with Vyvanse.

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

Vyvanse is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Vyvanse in a safe place to prevent misuse and abuse. Selling or giving away Vyvanse may harm others, and is against the law.

Tell your doctor if you or your child has ever abused or been dependent on alcohol, prescription medicines or street drugs.

Vyvanse is a stimulant medicine. Some people have had the following problems when taking stimulant medicines such as Vyvanse:

1. Heart-related problems including:

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

Tell your doctor if you or your child has any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor should check you or your child carefully for heart problems before starting Vyvanse.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with Vyvanse.

Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Vyvanse.

2. Mental (psychiatric) problems including:

In Children, Teenagers, and Adults:

- **new or worse behavior and thought problems**
- **new or worse bipolar illness**

In Children and Teenagers:

- **new psychotic symptoms such as:**
 - **hearing voices**
 - **believing things that are not true**
 - **being suspicious**
- **new manic symptoms**

Tell your doctor about any mental problems you or your child has, or about a family history of suicide, bipolar illness, or depression.

Call your doctor right away if you or your child has any new or worsening mental symptoms or problems while taking Vyvanse, especially:

- **seeing or hearing things that are not real**
- **believing things that are not real**
- **being suspicious**

What Is Vyvanse?

Vyvanse is a central nervous system stimulant prescription medicine. Vyvanse is used for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD). Vyvanse may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

It is not known if Vyvanse is safe and effective in children under 6 years of age.

Who should not take Vyvanse?

Do not take Vyvanse if you or your child:

- is taking or has taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI.
- is sensitive to, allergic to, or had a reaction to other stimulant medicines.

What should I tell my doctor before taking Vyvanse?

Before you or your child takes Vyvanse, tell your doctor if you or your child has or if there is a family history of:

- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression

Tell your doctor if:

- you or your child is pregnant or plan to become pregnant. It is not known if Vyvanse will harm your unborn baby.
- you or your child is breastfeeding or plan to breastfeed. Vyvanse passes into breast milk. Discuss with your doctor before you breastfeed while you are taking Vyvanse.

Tell your doctor about all of the medicines that you or your child takes, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Vyvanse can affect the way other medicines work, and other medicines may affect how Vyvanse works. Using Vyvanse with other medicines can cause serious side effects.

Especially tell your doctor if you or your child takes anti-depression medicines including MAOIs.

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Know the medicines that you or your child takes. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

Do not start any new medicine while taking Vyvanse without talking to your doctor first.

How should I take Vyvanse?

- Take Vyvanse exactly as your doctor tells you to take it.
- Your doctor may change your dose until it is right for you or your child.
- Take Vyvanse 1 time each day in the morning.
- Vyvanse can be taken with or without food.
- Vyvanse capsules may be swallowed whole.
- If you have trouble swallowing capsules, you may open your Vyvanse capsule and pour the powder into a glass of water.
 - Use all of the powder from the capsule so you get all of the medicine.

- Using a spoon, break apart any powder that is stuck together. Stir the powder and water until they are completely mixed together.
- Drink the entire glass of water right away after mixing. Do not store. It is normal to see a filmy coating on the inside of your glass after you drink all the medicine.
- Your doctor may sometimes stop Vyvanse treatment for a while to check your ADHD symptoms.
- Your doctor may do regular checks of your blood, heart, and blood pressure while taking Vyvanse.
- Children should have their height and weight checked often while taking Vyvanse. Vyvanse treatment may be stopped if a problem is found during these check-ups.
- If you or your child takes too much Vyvanse, call your doctor or poison control center right away, or get to the nearest hospital emergency room.

What should I avoid while taking Vyvanse?

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

What are 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

The most common side effects of Vyvanse include:

- | | |
|----------------------|----------------------|
| ○ anxiety | ○ loss of appetite |
| ○ decreased appetite | ○ nausea |
| ○ diarrhea | ○ trouble sleeping |
| ○ dizziness | ○ upper stomach pain |
| ○ dry mouth | ○ vomiting |
| ○ irritability | ○ weight loss |

Talk to your doctor if you or your child has any side effects that are bothersome or do not go away.

These are not all the possible side effects of Vyvanse. For more information ask your doctor or pharmacist.

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 at room temperature between 59°F to 86°F.
- Protect Vyvanse from light.
- Store Vyvanse in a safe place, like a locked cabinet.
- Do not throw away unused Vyvanse in your household trash as it may harm other people or animals. Ask your doctor or pharmacist about a medicine take-back program in your community.

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 condition. It may harm them.

This Medication Guide summarizes the most important information about Vyvanse. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Vyvanse that is written for healthcare professionals.

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

What are the ingredients in Vyvanse?

Active Ingredient: lisdexamfetamine dimesylate

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.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured for: Shire US Inc., Wayne, PA 19087.

© 2012 Shire US Inc.

Revised Month 2012