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MEDICATION GUIDE
VYVANSE®
(lisdexamfetamine dimesylate) CII

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 you or your child's treatment with Vyvanse.

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

Vyvanse is a stimulant medicine. The following have been reported with use of stimulant medicines.

1. Heart-related problems:

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

Tell your doctor if you or your child have 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 you 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:

All Patients

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

Children and Teenagers

- **new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms**

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

Call your doctor right away if you or your child have 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, or are suspicious.

What Is Vyvanse?

Vyvanse is a central nervous system stimulant prescription medicine. **It 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.

Vyvanse should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

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 have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take Vyvanse?

Vyvanse should not be taken if you or your child:

- have heart disease or hardening of the arteries
- have moderate to severe high blood pressure
- have hyperthyroidism
- have an eye problem called glaucoma
- are very anxious, tense, or agitated
- have a history of drug abuse
- are taking or have 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

Vyvanse has not been studied in children less than 6 years old. Vyvanse is not recommended for use in children less than 3 years old.

Vyvanse may not be right for you or your child. Before starting Vyvanse tell your or your child's doctor about all health conditions (or a family history of) including:

- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- tics or Tourette's syndrome
- liver or kidney problems
- thyroid problems
- seizures or have had an abnormal brain wave test (EEG)

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breastfeeding.

Can Vyvanse be taken with other medicines?

Tell your doctor about all of the medicines that you or your child take including prescription and non-prescription medicines, vitamins, and herbal supplements. Vyvanse and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted while taking Vyvanse.

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Your doctor will decide whether Vyvanse can be taken with other medicines.

Especially tell your doctor if you or your child takes:

- anti-depression medicines including MAOIs
- anti-psychotic medicines
- lithium
- blood pressure medicines
- seizure medicines
- narcotic pain medicines

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.

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

How should Vyvanse be taken?

- **Take Vyvanse exactly as prescribed.** Vyvanse comes in 6 different strength capsules. Your doctor may adjust the dose until it is right for you or your child.
- Take Vyvanse once a day in the morning.
- Vyvanse can be taken with or without food.
- From time to time, your doctor may stop Vyvanse treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the 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 or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of Vyvanse?

See **"What is the most important information I should know about Vyvanse?"** for information on reported heart and mental problems.

Other serious side effects include:

- slowing of growth (height and weight) in children
- seizures, mainly in patients with a history of seizures
- eyesight changes or blurred vision

Common side effects include:

- upper belly pain
- decreased appetite
- dizziness
- dry mouth
- irritability
- trouble sleeping
- nausea
- vomiting
- weight loss

Vyvanse may affect your or your child's ability to drive or do other dangerous activities.

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

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information

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 at room temperature, 59 to 86° F (15 to 30° C). Protect from light.
- **Keep Vyvanse and all medicines out of the reach of children.**

General information about 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 and it is against the law.

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 was written for healthcare professionals. For more information about Vyvanse, please contact Shire US Inc. at 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 contain gelatin, titanium dioxide, and one or more of the following: D&C Red #28, D&C Yellow #10, FD&C Blue #1, FD&C Green #3, and FD&C Red #40.

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

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