

PART III: CONSUMER INFORMATION


lisdexamfetamine dimesylate Capsules

This leaflet is Part III of a three-part "Product Monograph" published when VYVANSE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VYVANSE. Contact your doctor or pharmacist if you have any questions about the drug.

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

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 may wish to check you/your child carefully for heart problems before starting VYVANSE.

Your doctor may wish to check you/your child's blood pressure and heart rate regularly during treatment with VYVANSE.

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

Mental (Psychiatric) problems:

- New or worse behaviour and thought problems
- New or worse bipolar illness
- New or worse aggressive behaviour or hostility
- 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/your child have, or about a family history of suicide, bipolar illness, or depression.

Call your doctor right away if you/your child have any new or worsening mental symptoms while taking VYVANSE, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

ABOUT THIS MEDICATION

What the medication is used for:

VYVANSE is a central nervous system stimulant prescription medicine. It is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). VYVANSE capsules contain lisdexamfetamine dimesylate, the medicinal ingredient in the treatment of ADHD.

What it does:

Lisdexamfetamine dimesylate, the medicinal ingredient in VYVANSE, helps increase attention (including the ability to follow directions and finish tasks) and decrease impulsiveness and hyperactivity in patients with ADHD.

When it should not be used:

VYVANSE should not be taken if one or more of the following applies to you/your child:

- allergies to amphetamines or any of the other ingredients in VYVANSE (see: What the nonmedicinal ingredients are)
- heart disease or arteriosclerosis (hardened arteries)
- symptomatic cardiovascular disease
- moderate to severe high blood pressure
- agitated states
- glaucoma, an eye disease
- hyperthyroidism (an overactive thyroid gland)
- are taking or have taken medications from the group called monoamine oxidase inhibitors (MAOI) within the last 14 days
- have a history of drug abuse.

VYVANSE has not been studied, and is not recommended for use, in children less than 6 years old.

What the medicinal ingredient is:

Lisdexamfetamine dimesylate

What the nonmedicinal ingredients are:

Croscarmellose sodium, magnesium stearate and microcrystalline cellulose. The capsule shells contain gelatin, titanium dioxide, and one or more of the following: FD&C Yellow #6, FD&C Blue #1, FD&C Red #3, FDA/E172 Black Iron Oxide, FDA/E172 Yellow Iron Oxide.

What dosage forms it comes in:

20mg, 30mg, 40mg, 50mg and 60mg Capsules

WARNINGS AND PRECAUTIONS

VYVANSE may not be right for you/your child. Before you/your child use VYVANSE, talk to your doctor or pharmacist if one or more of the following applies to you/your child:

- heart disease or condition, structural heart abnormalities or high blood pressure
- family history of sudden death or death related to heart problems
- participate in strenuous exercise
- take other drugs for ADHD
- have abnormal thoughts or visions, hears abnormal sounds or voices, or has been diagnosed with psychosis presently or in the past
- have symptoms of depression (feelings of sadness, worthlessness or hopelessness) or bipolar disorder (mood swings), or have been diagnosed with depression or bipolar disorder presently or in the past
- family history of suicide, depression, or bipolar disorder
- have motion tics (hard to control, repeat twitching of any parts of the body) or verbal tics (hard to control repeating of sounds or words) or Tourette's syndrome
- have relatives with motion tics, verbal tics, or Tourette's syndrome
- have a history of seizures (convulsions, epilepsy) or have had an abnormal brain wave test (EEG).

Tell your doctor if you/your child develop any of the above condition or symptoms while taking VYVANSE.

Abuse of amphetamines can lead to dependence and possibly serious heart problems and death. Substance abuse may be less likely in patients with ADHD if they are treated with medication. VYVANSE should only be given under close medical supervision to patients whose condition has been properly diagnosed.

Tell your doctor if you/your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Sudden death has been reported with drugs used for ADHD treatment in individuals with structural heart abnormalities or other serious heart problems. VYVANSE generally should not be used in patients with known structural heart abnormalities, disease of the heart muscle, serious heart rhythm abnormalities or other serious heart disease or conditions.

VYVANSE may be a part of the patient's overall treatment for ADHD. The doctor may also recommend that you/your child have counseling or other therapy.

INTERACTIONS WITH THIS MEDICATION

It is important to tell your doctor or pharmacist about all medicines that you/your child are taking, including other medicines that a doctor has prescribed, medicines or vitamins that you buy yourself without a prescription, and any herbal remedies. While on VYVANSE, do not take/give your child a new medicine or herbal remedy before checking with you/your child's doctor.

Especially tell your doctor if you/your child take:

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

Know the medicines that you/your child take. Keep a list of your/your child's medicines with you to show the doctor and pharmacist.

Drugs that may interact with VYVANSE include:

- Urinary acidifying agents (ammonium chloride, sodium acid phosphate, etc.)
- Urinary alkalinizing agents (acetazolamide, some thiazides)
- Adrenergic blockers
- Antidepressants, tricyclic (desipramine, protriptyline, etc.)
- Monoamine oxidase inhibitor antidepressants, as well as furazolidone
- Antihistamines
- Antihypertensives
- Chlorpromazine
- Ethosuximide
- Haloperidol
- Lithium carbonate
- Meperidine
- Methamphetamine therapy
- Norepinephrine
- Phenobarbital
- Phenytoin
- Propoxyphene
- Veratrum alkaloids.

PROPER USE OF THIS MEDICATION

VYVANSE should be taken by mouth, once a day in the morning.

Capsules may be swallowed whole with water. Capsules may be opened and the entire contents dissolved in a glass of water and taken immediately; do not store for future use. The dose of a single capsule should not be divided. The contents of the entire capsule should be taken, and you/your child should not take anything less than one capsule per day. VYVANSE can be taken with or without meals.

In order to receive the most benefit from VYVANSE, it is important that VYVANSE be taken only as directed by your/your child's doctor. The doctor may adjust the amount of drug taken until it is right for you/your child. From time to time, the doctor may interrupt treatment to check your/your child's symptoms while you/your child are not taking the drug.

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.

As with all medicines, never share VYVANSE with anyone else and administer only the number of VYVANSE capsules prescribed by your/your child's doctor.

Overdose:

Possible symptoms of an overdose include: restlessness (urge to keep moving), tremor, hyperreflexia (exaggerated reflexes), rapid respiration, confusion, assaultiveness (aggression), hallucinations, panic states, hyperpyrexia (high fever) and rhabdomyolysis (muscle pain). Fatigue and depression usually follow the central nervous system stimulation. Cardiovascular effects include arrhythmias (irregular heartbeat), hypertension or hypotension (high or low blood pressure) and circulatory collapse (rapid drop in blood pressure). Gastrointestinal (digestive) symptoms include nausea, vomiting, diarrhea, and abdominal (stomach) cramps. Fatal poisoning is usually preceded by convulsions (seizures) and coma.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you/your child forget to take your/his or her dose in the morning, wait until the next day and take or have him or her take the usual dose at the usual time in the morning. Do not double dose.

Afternoon doses should be avoided because of the long-acting nature of the drug, including the potential for insomnia.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its desired effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur, talk to your doctor.

See above section on **WARNINGS AND PRECAUTIONS** 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:

- Decreased appetite
- Dizziness
- Dry mouth
- Headache
- Irritability
- Nausea
- Trouble sleeping
- Upper belly pain
- Vomiting
- Weight loss.

VYVANSE may affect your/your child's ability to perform dangerous activities.

VYVANSE in children may cause slower growth (slowed weight gain and/or height). The doctor will be carefully watching your/your child's height and weight. If you/your child are not growing or gaining weight as the doctor expects, the doctor may stop the patient's VYVANSE treatment.

Tell your doctor if you/your child have blurred vision when taking VYVANSE.

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

This is not a complete list of side effects. For any unexpected effects while taking VYVANSE, contact your doctor or pharmacist.

HOW TO STORE IT

Keep this medication out of the reach of children.

Store VYVANSE at 15 to 30°C. Protect from light.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

More information can be found on the internet at:
<http://www.vyvanse.ca>

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Last revised: 23 December 2011

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