

**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.**

**ABOUT THIS MEDICATION****What the medication is used for:**

VYVANSE is a central nervous system stimulant prescription medicine to be used only as follows:

- for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). 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.
- to treat moderate to severe Binge Eating Disorder (BED) in adults.

**Binge Eating Disorder:** Use of other stimulant drugs for weight loss has been associated with serious heart-related problems. It is not known if VYVANSE is safe and effective for weight loss.

**What it does:*****Attention Deficit Hyperactivity Disorder (ADHD):***

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.

***Binge Eating Disorder (BED):***

Lisdexamfetamine dimesylate, the medicinal ingredient in VYVANSE, may help reduce the number of binge eating days in adults with BED.

**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 or its container
- sensitive to, allergic to or had a reaction to other stimulant medicines
- advanced arteriosclerosis (hardened arteries)
- symptomatic heart 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
- are breastfeeding or plan to breastfeed. VYVANSE passes into breast milk.

VYVANSE has not been studied in, and should not be used in, children with ADHD less than 6 years old.

VYVANSE has not been studied and should not be used in children with BED (younger than 18 years of age).

**What the medicinal ingredient is:**

Lisdexamfetamine dimesylate

**What the nonmedicinal ingredients are:**

Croscarmellose sodium, magnesium stearate and microcrystalline cellulose. The capsule shells contain edible ink, gelatin, titanium dioxide (E171), and one or more of the following: FD&C Yellow #6 (E133), FD&C Blue #1 (E110), FD&C Red #3 (E127), FDA/E172 Black Iron Oxide, FDA/E172 Yellow Iron Oxide.

**What dosage forms it comes in:**

10mg, 20mg, 30mg, 40mg, 50mg, 60mg and 70mg Capsules

**WARNINGS AND PRECAUTIONS****Serious Warnings and Precautions**

**VYVANSE has a potential for abuse, misuse and dependence.**  
(see also Drug Abuse and Dependence below)

The following have been reported with use of medicines such as VYVANSE:

**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**

Sudden death has been reported with drugs used for ADHD treatment in children/adolescents with structural heart abnormalities or other serious heart problems. Although some serious heart problems alone can carry an increased risk of sudden death, VYVANSE generally should not be used in children, adolescents or adults with known structural heart abnormalities, disease of the heart muscle, serious heart rhythm abnormalities or other serious heart disease or conditions.

**Binge Eating Disorder:** There may be additional heart-related risks in overweight and obese patients.

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

doctor may wish to 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:**

- **New or worse thoughts or feelings related to suicide (thinking about or feeling like killing yourself) and suicide actions (suicide attempt, completed suicide)**
- **New or worse bipolar illness, characterized by extreme mood swings, with periods of mania (unusually excited, over-active or un-inhibited) alternating with periods of depression (feelings of sadness, worthlessness or hopelessness)**
- **New or worse aggressive behavior or hostility**
- **New psychosis (such as hearing voices, believing things that are not true, are suspicious) or new mania (unusually excited, over-active or un-inhibited).**

These new or worse mental problems may be more likely to occur if you/your child have mental disorders that you may or may not know about. Tell your doctor about any mental problems you or your child have, or about any personal or family history of suicide, bipolar illness, or depression.

A small number of patients taking ADHD drugs may experience unusual feelings of agitation, hostility or anxiety, or have impulsive or disturbing thoughts such as thoughts of suicide, self-harm or harm to others. Those suicidal thoughts or behaviors may occur at any time *during* treatment, particularly at the start or during dose changes, and also *after stopping* VYVANSE. **Should this happen to you, or to those in your care if you are a caregiver or guardian, talk to your doctor immediately. Close observation by a doctor is necessary in this situation.**

**Call your doctor right away if you or your child has 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.**

**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 or activities
- take other drugs for ADHD
- have mental problems, or family history of mental problems, including psychosis, mania, bipolar illness, depression or suicide

- have motor 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 motor tics, verbal tics, or Tourette's syndrome
- have a history of seizures (convulsions, epilepsy) or have had an abnormal brain wave test (EEG)
- are pregnant or plan to become pregnant. Taking VYVANSE during pregnancy can cause harm to your baby. If VYVANSE is required during pregnancy, the risk to the unborn baby should be weighed against the benefits for the mother. Your doctor can discuss these issues with you
- have kidney-related problems as your doctor may reduce the dose
- have circulation problems in fingers and toes, including numbness; feeling cold or pain. (This is also known as Raynaud's).

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

## **Drug Abuse and Dependence**

Amphetamines have the potential for abuse and misuse. 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 (see Serious Warnings and Precautions above).

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.

## **Growth in Children**

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. VYVANSE treatment may be stopped if you/your child are not growing or gaining weight as the doctor expects.

## **Dangerous activities**

Before you/your child perform tasks which may require special attention, such as riding a bike, driving, operating machinery or doing other dangerous activities, wait until you know how you/your child respond to VYVANSE.

## **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.

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:**

- Extended-release guanfacine, another medicine for ADHD
- Extended-release venlafaxine, a medicine used to treat depression and anxiety
- Medicines and conditions that make urine more acidic (e.g., ascorbic acid (vitamin C), ammonium chloride, sodium acid phosphate)
- Medicines and conditions that make urine more alkaline (e.g., sodium bicarbonate, acetazolamide, thiazides)
- Medicines to treat depression including monoamine oxidase inhibitors (MAOIs), selective serotonin reuptake inhibitors (SSRIs) and serotonin and noradrenaline reuptake inhibitors (SNRIs)
- Anti-psychotic medicines chlorpromazine, haloperidol and pimozide
- Modafinil
- Medicines used to reduce or increase blood pressure.

**PROPER USE OF THIS MEDICATION**

Capsules may be swallowed whole with water. Capsules may be opened and the entire contents mixed with yogurt or in a glass of water or orange juice; any compacted powder should be completely broken apart with a spoon. Consume entire yogurt or drink all water or orange juice **immediately**; do not store for future use. A film of inactive ingredients may remain in the glass or container after the mixture is consumed. 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.

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. If you/your child have kidney-related problems, your doctor may reduce the dose. 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 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.

*Attention Deficit Hyperactivity Disorder (ADHD)* (Adults and Children 6 years of age and older):

**Usual dose:** 20mg to 60mg once a day in the morning, with or without food.

Follow your doctor's instructions on how to take your dose.

*Binge Eating Disorder (BED)* (Adults):

**Starting Dose:** 30mg once a day in the morning with or without food.

**Usual Dose:** 50mg to 70mg once a day in the morning with or without food.

Follow your doctor's instructions on how to take your dose.

**Overdose:**

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**

When used in ADHD, the most common side effects may include:

- Anorexia, decreased appetite, nausea, vomiting, upper belly pain, diarrhea, dizziness
- Dry mouth
- Headache
- Irritability
- Trouble sleeping
- Weight loss.

When used in BED, the most common side effects may include:

- Constipation, decreased appetite, diarrhea, nausea
- Dry mouth
- Trouble sleeping
- Feeling jittery/restless/racing thoughts
- Headache
- Irritability
- Increased heart rate
- Fatigue
- Anxiety
- Common cold, upper respiratory infection
- Excessive sweating

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	<b>Uneven heartbeat (palpitations)</b> (see Warnings and Precautions)		√	
	<b>Slowing of growth (height and weight) in children</b>		√	
	<b>Anxiety</b>	√		
	<b>New tics</b>		√	
Uncommon	<b>Allergic Reaction:</b> Rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
	<b>Trouble with Vision:</b> Eyesight changes or blurred vision		√	
	<b>New Psychotic or Manic Symptoms:</b> -Paranoia, delusions -Hallucinations: seeing, feeling or hearing things that are not real -Mania: feeling unusually excited, over-active, or uninhibited (see Warnings and Precautions)		√	
	<b>Aggressive Behavior or Hostility</b>		√	
	<b>Depression:</b> Feeling sad, loss of interest in usual activities, hopelessness, insomnia, or sleeping too much		√	

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Unknown	<b>Fits (seizures)</b>			√
	<b>Liver Disorder (eosinophilic hepatitis):</b> Allergic liver injury seen as possible yellowing of the eyes and/or skin, dark urine, abdominal pain, nausea, vomiting, loss of appetite			√
	<b>Suicidal Behavior:</b> Thoughts or actions about hurting or killing yourself. (see Warnings and Precautions)			√
	<b>Serious Skin Condition (Stevens-Johnson Syndrome):</b> Swelling of the skin (angioedema) or serious skin rash seen as severe blisters of the skin and mucous membranes			√
	<b>Cardiomyopathy:</b> Breathlessness or swelling of the legs (signs of heart muscle disease) (see Warnings and Precautions)		√	
	<b>Raynaud's Phenomenon:</b> discoloration of the fingers and toes, pain, sensations of cold and/or numbness		√	

*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 sight and 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](http://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 1908C
    - 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](http://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****If you want more information about VYVANSE:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website <http://hc-sc.gc.ca> ; the manufacturer's website [www.shirecanada.com](http://www.shirecanada.com) , or by calling 1-800-268-2772.

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