

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Vyvanse 30 mg capsules
Vyvanse 50 mg capsules
Vyvanse 70 mg capsules

Active ingredient and quantity:

Each capsule of Vyvanse 30 contains: lisdexamfetamine dimesylate 30 mg

Each capsule of Vyvanse 50 contains: lisdexamfetamine dimesylate 50 mg

Each capsule of Vyvanse 70 contains: lisdexamfetamine dimesylate 70 mg

Warning: dependence, abuse, and addiction

Vyvanse has a high potential for dependence, addiction and abuse which can lead to development of a substance use disorder, including addiction. Dependence and abuse of central nervous system stimulants, including Vyvanse, can lead to overdose and death.

Inactive ingredients and allergens – See section 6 “Additional information”.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

The medicine is not intended for children under the age of 6 years who have ADHD or patients under 18 years old with binge eating disorder (BED).

1. What is this medicine intended for?

Vyvanse is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Vyvanse can help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Vyvanse is intended for treating moderate to severe binge eating disorder. It may reduce the number of binge eating days in BED patients.

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

Vyvanse is intended only for patients over the age of 6 years who have ADHD and for patients over the age of 18 years with BED.

Therapeutic group: CNS stimulant.

It is not known if Vyvanse is safe and effective in children with ADHD under 6 years old or in patients with BED under 18 years old.

2. Before using this medicine

Do not use this medicine if:

- You or your child is sensitive (allergic) to the active ingredient (lisdexamfetamine dimesylate) or to any of the other ingredients in this medicine (see section 6 – "Additional information").
- You or your child is taking or has taken within the past 14 days an anti-depression medicine from the monoamine oxidase inhibitors (MAOIs) group.
- You or your child is sensitive to, allergic to, or had an allergic reaction to other medicines that stimulate the central nervous system.
- You were treated with the antibiotic linezolid or intravenous methylene blue.

Special warnings about using this medicine

- Vyvanse is a medicine defined as a controlled substance because it can lead to dependence or be abused. Keep the medicine in a safe place to prevent misuse and abuse.
- Keep Vyvanse in a safe place to protect it from theft. 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 which may cause the following problems in some of the users:

a. Heart-related problems:

- 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 defect, 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. Inform your doctor immediately if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Vyvanse.

b. Mental (psychiatric) problems including:

- New or worse behavior and thought problems
- New or worse bipolar illness
- New psychotic symptoms
- Hearing voices
- Believing things that are not true
- Being suspicious
- 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 immediately if during treatment with Vyvanse you or your child have any new or worsening mental symptoms or problems, especially:

- Seeing or hearing things that are not real
- Believing things that are not real
- Being suspicious

c. Circulation problems in fingers and toes (Peripheral vasculopathy, including Raynaud's phenomenon):

- Fingers or toes may feel numb, cool, painful
- Fingers or toes may change color from pale, to blue, to red
- Tell your doctor if you or your child has **numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes**
- Call your doctor right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking Vyvanse

Before using Vyvanse, tell your doctor if:

- You or your child has or if there is a family history of:
 - Heart problems, heart defects, heart disease, high blood pressure
 - Mental problems such as: psychosis, mania, bipolar illness, or depression

- Circulation problems in fingers or toes
- Kidney problems. Your doctor may lower your dose
- **Repeated movements or sounds (tics) or Tourette's syndrome**

Tests and follow-up

During the treatment period, you may also be referred for regular blood tests, heart and blood pressure tests.

Children should have their height and weight checked often while taking Vyvanse. Vyvanse treatment may be stopped if your child is not growing or gaining weight. Your doctor may stop the treatment with Vyvanse in order to check ADHD or BED symptoms.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- Selective serotonin reuptake inhibitors (SSRIs)
- Serotonin norepinephrine reuptake inhibitors (SNRIs)
- Medicines used to treat migraine headaches called triptans
- Lithium
- Fentanyl
- Tramadol
- Tryptophan
- Buspirone
- St. John's Wort
- Anti-depression medicines including monoamine oxidase inhibitors (MAOIs), such as: selegiline, isocarboxazid, phenelzine, tranylcypromine (see also the section "Do not use this medicine if")
- Vitamin C (ascorbic acid)
- Baking soda (bicarbonate)
- Substances that make your urine more alkaline like acetazolamide, thiazides
- Substances that make your urine more acidic like ammonium chloride, sodium acid phosphate, methenamine salts
- Tricyclic antidepressants such as desipramine, protriptyline

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

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

Using this medicine and food

The capsule can be taken with or without food.

Using this medicine and alcohol consumption

It is not recommended to drink alcohol during treatment with Vyvanse. Alcohol may worsen any side effects which appear during treatment with Vyvanse.

Pregnancy and breastfeeding

Breastfeeding during treatment with Vyvanse is not recommended. If you are pregnant or might be pregnant, consult your doctor before using this medicine.

The medicine passes into breast milk. If you are breastfeeding or plan to breastfeed, Consult your doctor before using this medicine.

Driving and using machines

Do not drive or use dangerous machines while using the medicine until you know how Vyvanse affects you.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.
Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.
The recommended dosage is usually:
Take one dose of Vyvanse each morning.

Taking Vyvanse capsules:

- Vyvanse capsules may be swallowed whole.
- If you have trouble swallowing the capsule, you may open it:
 - Mix the powder with yogurt, water, or orange juice.
 - Use all the Vyvanse powder in the capsule to be sure that you get all the medicine.
 - Use a spoon to break apart any powder that is stuck together.
 - Stir the powder and water/yogurt/orange juice until they are completely mixed together.
 - Drink the entire glass right away after mixing. **Do not store the yogurt, water or orange juice mixture.**
 - It is normal to see a filmy coating on the inside of your glass after you drink all the medicine.

Do not exceed the recommended dose.

If you have accidentally taken a higher dose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, take the next dose at the usual time and consult your doctor. **Do not take a double dose.**
Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Vyvanse may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Consult your doctor immediately if you have any of the following side effects:

- **Slowing of growth (height and weight) in children**
- **Circulation problems in the blood vessels of the fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon).** Symptoms may include:
 - Fingers or toes may feel numb, cool, painful
 - Fingers or toes may change color from pale, to blue, to redTell your doctor if you or your child have numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.
Call your doctor 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 doctor if you or your child have any new or worsening tics or worsening Tourette's syndrome during treatment with Vyvanse.
- **Serotonin syndrome** - A potentially life-threatening problem may happen when Vyvanse is taken with certain other medicines. Stop taking Vyvanse and call your doctor 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
- Hallucination (seeing or hearing things that are not real)
- Changes in blood pressure
- High body temperature (hyperthermia)
- Nausea, vomiting, diarrhea

Very common side effects in children 6 to 17 years old and adults with ADHD (effects that appear in more than one in ten users):

- Loss of appetite (anorexia)
- Decreased appetite
- Diarrhea
- Anxiety
- Weight loss
- Dizziness
- Nausea
- Vomiting
- Trouble sleeping
- Dry mouth
- Irritability
- Upper stomach pain
- Headache

Common side effects of Vyvanse in patients with ADHD (effects that appear in up to 1-10 in 100 users):

- Anxiety
- Nausea
- Weight loss
- Diarrhea
- Dizziness
- Vomiting
- Tremor
- Rash
- Mood swings
- Fever
- Sleepiness or tiredness
- Feeling jittery, agitated or restless
- Increased blood pressure
- Excessive sweating
- Unable to get or keep an erection
- Decreased sex drive
- Being unusually active
- Rapid heart rate
- Difficulty breathing
- Tics
- Anorexia
- Dry mouth
- Palpitations

- Abnormal ECG results showing ventricular hypertrophy
- Psychomotor hyperactivity

Uncommon side effects of Vyvanse in patients with ADHD (effects that appear in 1-10 in 1000 users):

- Excessive talkativeness (logorrhea)
- Chest pain
- Anger
- Obsessive skin scratching
- Headache
- Depression
- Paranoia

Very common side effects of Vyvanse in patients with BED (effects that appear in more than one in ten users):

- Dry mouth
- Insomnia

Common side effects of Vyvanse in patients with BED (effects that appear in 1-10 in 100 users):

- Decreased appetite
- Increased heart rate
- Feeling jittery
- Constipation
- Anxiety
- Diarrhea
- Weight loss
- Increased sweating
- Vomiting
- Inflammation of the stomach and bowel
- Paresthesia (feeling prickles on your skin for no apparent reason)
- Itch
- Upper abdominal pain
- Increased energy
- Urinary tract infection
- Nightmares
- Restlessness
- Pain in the lower part of your throat

Uncommon side effects of Vyvanse in patients with BED (effects that appear in 1-10 in 1000 users):

- Increased heart rate
- Headache
- Upper abdominal pain
- Difficulty breathing
- Rash
- Trouble sleeping
- Hypersensitivity
- Irritability
- Anxiety

Side effects of unknown frequency:

- Palpitations, cardiomyopathy
- Mydriasis - excessive widening of the pupils of the eyes
- Diplopia – double vision
- Blurred vision or difficulty focusing on objects
- Eosinophilic hepatitis - allergic liver injury seen as possible yellowing of the eyes and/or skin

- Severe allergic reaction characterized by a sharp drop in blood pressure, difficulty breathing and hives/itching
- Hypersensitivity
- Uncontrolled involuntary movements
- Bad taste in your mouth
- Tics
- Grinding of the teeth
- Depression
- Compulsive scratching of the skin
- Hair loss
- Aggressiveness
- Stevens-Johnson syndrome
- Chest pain
- Angioedema
- Urticaria
- Seizures
- Changes in sex drive
- Frequent or prolonged erections
- Constipation
- Disintegration of muscle tissue (rhabdomyolysis)
- Intestinal ischemia

Reporting side effects

You can report side effects to the Ministry of Health by following the link "Reporting Side Effects of Drug Treatment" on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store at a temperature below 25°C.
- Protect Vyvanse from light.
- Store in the original package.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

microcrystalline cellulose, croscarmellose sodium, magnesium stearate

Composition of the empty capsule -

gelatin, titanium dioxide

Vyvanse 30 mg: FD&C Red #3, FD&C Yellow #6

Vyvanse 50 mg: FD&C Blue #3

Vyvanse 70 mg: FD&C Red #3, FD&C Yellow #6

What the medicine looks like and contents of the pack:

30 mg: white body/orange cap imprinted with 30 mg and S489, bottles of 28, 30 or 100 capsules
50 mg: white body/blue cap imprinted with 50 mg and S489, bottles of 28, 30 or 100 capsules
70 mg: blue body/orange cap imprinted with 70 mg and S489, bottles of 28, 30 or 100 capsules.

Not all packs may be marketed.

Registration holder's name and address: Medison Pharma Ltd., 10 Hashiloach St., P.O
Box 7090, Petach Tikva

Manufacturer's name and address:
Shire Pharmaceutical Contracts Ltd.,
1 Kingdom Street
London, W2 6BD
United Kingdom

This leaflet was revised in May 2024.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Vyvanse 30 mg: 153-19-33994-00

Vyvanse 50 mg: 153-20-34001-00

Vyvanse 70 mg: 153-21-34000-00

VYVANSE PIL-0524-V2