VYVANSE® capsules

Lisdexamfetamine dimesilate

Consumer Medicine Information

What is in this leaflet

Please read this leaflet before you/your child start taking VYVANSE.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine. Those updates may contain important information about the medicine and its use of which you should be aware.

This leaflet answers some common questions about VYVANSE.

It does not contain all available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you or your child taking VYVANSE against the benefit it is expected to have.

If you have any concerns about taking VYVANSE, talk to your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again.

What VYVANSE is used for

VYVANSE is used to treat Attention Deficit Hyperactivity Disorder (ADHD). VYVANSE is a central nervous system stimulant that increases attention and decreases impulsiveness and hyperactivity in patients with ADHD. It is not to be taken by children younger than 6 years of age. VYVANSE should be used as part of a comprehensive treatment program which usually includes psychological, educational and social therapy.

The main ingredient in VYVANSE is lisdexamfetamine dimesilate which itself is not active (such medicines are sometimes called a pro-drug). After VYVANSE is taken, it is converted in the blood to dexamphetamine which is the active medicine.

Your doctor may have prescribed VYVANSE for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you/your child.

VYVANSE can be abused or lead to dependence. VYVANSE is a controlled substance and should be handled responsibly. It is illegal for anyone prescribed VYVANSE to sell or give it to other people.

Keep VYVANSE in a safe place to prevent misuse and abuse. Also, return any unused capsules to your pharmacy to safeguard against them being taken by anyone else (see Disposal section).

Before you take VYVANSE

VYVANSE capsules are not suitable for everyone.

When you must not take it

Do not take VYVANSE if you/your child:

- have a disease of the arteries due to cholesterol deposits e.g. atherosclerosis
- are allergic (hypersensitive) to amphetamines or any of the other ingredients of VYVANSE listed in "Other ingredients" section of this leaflet
- have heart disease such as angina or myocardial infarction (heart attack)
- have moderate to severe high blood pressure
- have hyperthyroidism (hyperactive thyroid)
- have an eye condition called glaucoma
- have a tumour of the adrenal gland tissue (phaeochromocytoma)
- have tics (muscle twitching usually in the face and shoulders)
- have Tourette's syndrome
- have severe depression, suicidal ideation or behaviour, thoughts or acts of self-harm or mental illness
- have periods of severe anxiety, tension or agitation
- suffer with drug dependence or abuse alcohol
- are taking or have taken an antidepressant called a monoamine oxidase inhibitor or MAOI within the past 14 days.

Do not use VYVANSE if the bottle shows signs of tampering.

Do not use VYVANSE beyond the expiry date (month and year) printed on the bottle.

If you/your child take VYVANSE after the expiry date has passed, it may have no effect, or worse, there may be an entirely unexpected effect.

Do not give it to children unless your doctor has prescribed it. VYVANSE is not recommended for use in children under 6 years of age.

If you are not sure whether you/your child should start using VYVANSE, contact your doctor.

Before you take it

Tell your doctor or pharmacist if you or your child:

- are allergic to any other medicines, or any foods, dyes or preservatives
- are pregnant or planning to become pregnant
- are breastfeeding or wish to breastfeed
- have any other medical conditions or heart problems, including ischaemic heart disease (such as angina or myocardial infarction), suspicion or presence of any cardiac or heart-related abnormalities, irregular heartbeats or rate, family history of sudden/cardiac death
- suffer from blood pressure and/or taking medications to treat blood pressure
- disorders of the blood vessels of the brain e.g. stroke
- suffer from depression, bipolar disorder, or schizophrenia or other mental illness
- have liver or kidney disease. Your doctor may lower the dose if you have kidney disease.
- have epilepsy or other seizures or have had an abnormal brain wave test (EEG)
- are experiencing growth difficulties.

Your doctor may ask you to stop taking VYVANSE for a short time before certain radioactive imaging medicine. Some medicines may reduce the quality of the picture obtained during an imaging procedure.

If you have not told your doctor or pharmacist about any of the above, tell them before you/your child take any VYVANSE.

Taking other medicines

Tell your doctor or pharmacist about all the medicine you/your child are taking or have recently taken, 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.

It is especially important to tell your doctor or pharmacist if you or your child is taking medicines to treat any of the following conditions:

- depression, including class of medicines called monoamine oxidase inhibitor (MAOIs). Taking an MAOI with VYVANSE may cause a sudden increase in your blood pressure. Severe outcomes including death may occur
- anxiety, mania or bipolar disorder
- high blood pressure
- schizophrenia or schizophrenia-like illness
- strong pain

In addition, the following medicines may also interact with VYVANSE:

- Urinary acidifying agents e.g. ascorbic acid (Vitamin C), ammonium chloride, sodium acid phosphate
- Urinary alkalinising agents e.g. sodium bicarbonate, acetazolamide, some thiazides
- Medicines that can raise the level of serotonin (a chemical in your brain), including classes of medicines called selective serotonin reuptake inhibitors (SSRIs), serotonin and noradrenaline reuptake inhibitors (SNRIs), and amphetamines. If you do take VYVANSE with these medicines, you may experience elevated body temperature, muscle stiffness, involuntary muscle jerking, fluctuations of vital signs (blood pressure, heart rate, breathing rate) and mental state from extreme agitation progressing to confusion and coma (a condition called serotonin syndrome).

Tell your doctor or pharmacist if you/your child are taking or have recently taken other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

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

How to take VYVANSE

Follow all directions given to you by your pharmacist or doctor carefully as this may differ from the information contained in this leaflet.

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 do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

How much to take

The usual starting dose for children, adolescents and adults is 30 mg once a day, but your doctor may decide to start you/your child on 20 mg once a

day. The dose may be increased until it is right for you or your child.

How to take it

- Take VYVANSE exactly as prescribed. VYVANSE comes in 6 different strengths of capsules.
- Take VYVANSE once a day in the morning.
- VYVANSE can be taken with or without food.
- If you have trouble swallowing capsules, you may open your VYVANSE capsule and pour all of the powder into a soft food such as yoghurt, water or orange juice.
- Use all of the VYVANSE powder from the capsule so you get all of the medicine.
- Using a spoon, break apart any powder that is stuck together. Stir the VYVANSE powder and yoghurt, water or orange juice until they are completely mixed together.
- Consume all of the yoghurt, water or orange juice right away after it has been mixed. Do not store the yoghurt, water or orange juice after it has been mixed with VYVANSE.
- Do not worry if there is a film or residue left in the glass or container afterwards - this is not the active ingredient.
- From time to time, your doctor may stop VYVANSE treatment for a while to check ADHD symptoms.

If you forget to take it

If you/your child forget to take your capsules then take them as usual the next morning. Do not take a double dose to make up for a forgotten capsule.

Avoid taking VYVANSE in the afternoon or evening as it can cause an inability to sleep.

A Dosage Chart is provided on the VYVANSE carton to help track the capsules are taken properly. Cross off a symbol each time a capsule is taken.

If you take too much

Immediately telephone your doctor or the Poisons Information Centre (telephone 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you/your child or anyone else may have used too much VYVANSE. Do this even if there are no signs of discomfort or poisoning.

Some of the symptoms of an overdose includes restlessness, tremor, overactive or overresponsive bodily reflexes, rapid breathing, confusion, aggression, hallucinations, panic states, very high fever and other features of serotonin syndrome. Cardiovascular effects include, irregular heartbeat, high or low blood pressure. Gastrointestinal symptoms include, nausea, vomiting, diarrhoea, abdominal cramps, convulsion, coma. Headache, altered mental status, seizures and visual disturbances were also reported.

While you are taking VYVANSE

Things you must do

- VYVANSE should be taken in the morning
- Make sure that all of your doctors, dentists, ophthalmologists, psychologists and pharmacists know you/your child are taking VYVANSE. Remind them if any new medicines are about to be started.
- Like all stimulants, VYVANSE may become habit-forming and can be abused by some people. If it is taken correctly as instructed by your doctor, this should not happen, either now or later in life.
- Be sure to keep all doctors' appointments so that you/your child's progress can be checked.
- Your doctor will want to check your/your child's blood pressure and pulse.
- If you have a family history of sudden/cardiac death your doctor will assess you for presence of cardiac disease and undertake further cardiac evaluation.
- Your doctor may monitor you/your child's height and weight closely whilst on this medicine.
- Tell your doctor immediately if you/your child become pregnant while on VYVANSE.

Things you must not do

- Do not stop treatment or change the dosage without checking with your doctor
- Do not give VYVANSE to anyone else, even if they have the same condition as you/your child. It may not be safe for another person to take VYVANSE
- Do not take VYVANSE to treat any other complaints unless your doctor tells you to. It may not be safe to use VYVANSE for another complaint
- Do not take VYVANSE for a longer time than your doctor has prescribed.

Things to be careful of

Do not drive or operate machinery until you know how VYVANSE affects you

VYVANSE may cause dizziness, drowsiness and blurry or double vision. This is uncommon; but if affected, you/your child should avoid driving or using heavy machinery. Check with your doctor if driving is advisable for you/your child while you/your child are taking VYVANSE.

Be careful when drinking alcohol while taking VYVANSE

If you/your child drink alcohol, it could make some of the unwanted side effects of VYVANSE worse. Your doctor may suggest that you/your child avoid alcohol completely or reduce the amount you drink while you are taking VYVANSE.

Side effects

Tell your doctor or pharmacist as soon as possible if you/your child feel unwell while you/your child are taking VYVANSE.

Like all medicines, VYVANSE can cause some side effects. Sometimes they are serious, most of the time they are mild and temporary.

Do not be alarmed by this list of possible side effects. You/your child may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you/your child notice any of the following and they worry you:

- decreased or loss of appetite
- trouble sleeping
- headache
- dry mouth
- weight loss
- upper belly pain
- agitation, anxiety, aggression, affect lability, irritability, feeling jittery, feeling tired, feeling sleepy
- dizziness, restlessness, excessive motor activity with or without feelings of restlessness, tic, tremor
- rapid heartbeat (tachycardia), palpitations, increased blood pressure, sudden chest pain, shortness of breath or fainting
- nausea, vomiting, diarrhoea
- Obsessive-compulsive disorder (OCD) (including irresistible urge to pull out body hair, skin picking, having repeated unwanted thoughts, feelings, images or urges in your mind (obsessive thoughts), performing repeated behaviours or mental rituals (compulsions))
- dry eyes
- involuntary clenching or grinding of the teeth
- rash, fever, shortness of breath
- excessive sweating
- excessive widening of the pupil
- decreased sex drive, erectile dysfunction
- a less than normal height or weight for your child age group may result with long term use.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you/your child develop:

- allergic reaction which may result in a rash or more rarely to a sharp drop in blood pressure, difficulty breathing, and hives/itching (anaphylactic reaction)
- chest pain or tightness in the chest
- shortness of breath
- irregular heart beat
- seizures (fits)
- vision problems
- mood changes such as depression or irritability
- new or worsening aggressive behaviour
- excitement, overactivity and uninhibited behaviour
- confusion, delusion or hallucinations (seeing or feeling things that are not really there)
- abnormal thinking (psychosis)

These may be serious side effects. You/your child may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you/your child notice anything that is making you/your child feel unwell.

Other side effects not listed above may also occur in some people.

After taking VYVANSE

Storage

- **Keep the capsules in the bottle until it is time to take them.**
- **Keep medicines where children cannot see or reach them.**

  A locked cupboard at least one-and-a-half metres (1.5m) above the floor is a good place to store medicines.
- **Store VYVANSE in a cool dry place where the temperature is below 25°C. Keep the container tightly closed.**

  Do not store VYVANSE or any other medicines in the bathroom or near a sink. Do not leave medicines in the car or on windowsills. Heat and dampness can destroy medicines.

Disposal

Return any unused or out of date medicine to your pharmacist. Do not keep unused or expired VYVANSE as it can be abused or taken by someone else. Do not throw out with your household waste.

It is illegal for anyone prescribed VYVANSE to sell or give it to other people.

Product description

What VYVANSE looks like

VYVANSE 20 mg capsule: ivory opaque body and ivory opaque cap, printed ‘S489’ and ‘20 mg’ in black ink.

VYVANSE 30 mg capsule: white opaque body and pink opaque cap,

printed 'S489' and '30 mg' in black ink.

VYVANSE 40 mg capsule: white opaque body and blue/green opaque cap, printed ‘S489’ and ‘40 mg’ in black ink.

VYVANSE 50 mg capsule: white opaque body and blue opaque cap, printed 'S489' and '50 mg' in black ink.

VYVANSE 60 mg capsule: aqua blue opaque body and aqua blue opaque cap, printed ‘S489’ and ‘60 mg’ in black ink.

VYVANSE 70 mg capsule: blue opaque body and pink opaque cap, printed 'S489' and '70 mg' in black ink.

VYVANSE is supplied in bottles of 30 capsules, inside a cardboard box.

Ingredients

Active ingredient

The active ingredient is lisdexamfetamine dimesilate

Other ingredients

The inactive ingredients are: microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. The capsule shells contain gelatin, titanium dioxide (E171) (all strengths), erythrosine (E127) (30 mg and 70 mg), brilliant blue (E133) (40 mg, 50 mg, 60 mg and 70 mg), iron oxide yellow (20 mg and 40 mg), iron oxide black (40 mg) and TekPrint SW-9008 (all strengths).

Sponsor

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This leaflet was prepared in September 2026.

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