

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using VYVANSE?

VYVANSE contains the active ingredient lisdexamfetamine dimesilate. VYVANSE is used to treat 1) Attention Deficit Hyperactivity Disorder (ADHD) AND 2) Binge Eating Disorder (BED).

For more information, see Section [1. Why am I using VYVANSE?](#) in the full CMI.

2. What should I know before I use VYVANSE?

Do not use if you: have ever had an allergic reaction to VYVANSE or any of the ingredients listed at the end of the CMI; taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) or have taken an MAOI in the last 14 days; have a thyroid problem; feel unusually excited, over-active, or un-inhibited; have ever had heart problems.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use VYVANSE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VYVANSE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use VYVANSE?

- Take VYVANSE capsule once a day in the morning with or without food. The usual starting dose is 30 mg once a day, your doctor may change the dose until it is right for you. If you have trouble swallowing capsules, you may open your VYVANSE capsule and pour all of the powder into a soft food such as yogurt, water or orange juice; mix completely and consume mixed contents right away.
- Follow all directions given to you by your doctor or pharmacist carefully.

More instructions can be found in Section [4. How do I use VYVANSE?](#) in the full CMI.

5. What should I know while using VYVANSE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you/your child visit/s that you/your child are/is using VYVANSE. If you/your child become/s pregnant while using this medicine, tell the doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or change dosage without checking with your/your child's doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you/your child know/s how VYVANSE affects you/your child.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol while taking VYVANSE, it could make some of the unwanted side effects of VYVANSE worse.
Looking after your medicine	<ul style="list-style-type: none">• Store VYVANSE in a cool dry place where the temperature is below 25°C. Keep the container tightly closed.

For more information, see Section [5. What should I know while using VYVANSE?](#) in the full CMI.

6. Are there any side effects?

Common side effects include decreased appetite, insomnia, dry mouth, headache, upper abdominal pain, weight decreased, feeling tired. Serious side effects include allergic reaction, chest pain, shortness of breath, mood changes, confusion, seizures.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING: 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.

VYVANSE®

Active ingredient: lisdexamfetamine dimesilate

Consumer Medicine Information (CMI)

This leaflet provides important information about using VYVANSE. It does not take the place of talking to your doctor or pharmacist. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using 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. You can also download the most up to date leaflet from www.takeda.com/en-au. Those updates may contain important information about the medicine and its use of which you should be aware.

Where to find information in this leaflet:

- [1. Why am I using VYVANSE?](#)
- [2. What should I know before I use VYVANSE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use VYVANSE?](#)
- [5. What should I know while using VYVANSE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using VYVANSE?

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 ingredient. VYVANSE is a central nervous system stimulant.

VYVANSE is used to treat:

- Attention Deficit Hyperactivity Disorder (ADHD). VYVANSE increases attention and decreases impulsiveness and hyperactivity in patients with ADHD.
- Binge Eating Disorder (BED). VYVANSE may help to reduce the number of binge eating days in patients with moderate to severe BED.

VYVANSE is not for weight loss.

It is not to be taken by children with ADHD under 6 years of age or in patients with BED under 18 years of age. VYVANSE should be used as part of a comprehensive treatment program which usually includes psychological, educational and social therapy. For BED, VYVANSE should only be prescribed by a psychiatrist as part of a comprehensive treatment program.

2. What should I know before I use VYVANSE?

Warnings

Do not use VYVANSE if you:

- have a disease of the arteries due to cholesterol deposits e.g. atherosclerosis
- are allergic to amphetamines, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- 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 (MAOI) within the past 14 days.

Check with your doctor if you:

- are allergic to any other medicines, or any foods, dyes or preservatives
- take any medicines for any other condition
- have any other medical conditions or heart problems, including ischemic 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
- have a family or medical history of irregular heart rhythm (visible on an electrocardiogram), or if you have a disease and/or take a treatment that make(s) you prone to heartbeat irregularities or salt imbalances
- 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 illness, 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)
- have circulation problems in fingers and toes
- are experiencing growth difficulties.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with VYVANSE and affect how it works.

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 (MAOI). 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).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VYVANSE.

4. How do I use VYVANSE?

How much to take

- The usual starting dose for children, adolescents and adults is 30 mg once a day. Your doctor may increase the dose until it is right for you or your child. For treatment of BED your psychiatrist will assess the response to VYVANSE after 12 weeks.
- Follow the instructions provided and use VYVANSE until your doctor tells you to stop.

When to take VYVANSE

- Take VYVANSE once a day in the morning.

How to take VYVANSE

- 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 yogurt, 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 yogurt, water or orange juice until they are completely mixed together.
- Consume all of the yogurt, water or orange juice right away after it has been mixed. Do not store the yogurt, 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 your/your child's ADHD or your BED symptoms.

If you forget to use VYVANSE

VYVANSE should be used regularly in the morning each day. If you miss your dose, then take VYVANSE as usual the next morning. Avoid taking VYVANSE in the afternoon or evening as it can cause an inability to sleep.

Do not take a double dose to make up for the dose you missed.

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 use too much VYVANSE

If you think that you have used too much VYVANSE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia; 0800 POISON or 0800 764766 in New Zealand**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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.

5. What should I know while using VYVANSE?

Things you should 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 should 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may make some of the unwanted side effects of VYVANSE worse. Your doctor may suggest that you avoid alcohol completely or reduce the amount you drink while you are taking VYVANSE.

Looking after your medicine

Keep the capsules in the bottle until it is time to take them. Store VYVANSE in a cool dry place where the temperature is below 25°C. Keep the container tightly closed.

Do not store it in the bathroom or near a sink, or in the car or on windowsill.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal. 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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • decreased or loss of appetite • trouble sleeping • headache • dry mouth • feeling agitated, anxious, or irritable • feeling tired, sleepy • decreased sex drive, erectile dysfunction • weight loss • upper belly pain • nausea, vomiting, diarrhoea • involuntary clenching or grinding of the teeth • excessive sweating • excessive widening of the pupil • aggression, mood swings, feeling jittery • dizziness, restlessness, excessive motor activity with or without feelings of restlessness, tic, tremor • rapid heartbeat (tachycardia), palpitations, increased blood pressure • rash, fever • circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon): Fingers or toes may feel numb, cool, painful; change colour or have sensitivity to temperature • a less than normal height or weight for your child age group may result with long term use. • nosebleeds 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 heartbeat • seizures (fits) • vision problems • mood changes such as depression or irritability 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> 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) sudden, severe belly pain 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What VYVANSE contains

Active ingredient (main ingredient)	Lisdexamfetamine dimesilate
Other ingredients (inactive ingredients)	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).

Do not take this medicine if you are allergic to any of these ingredients.

What VYVANSE looks like

VYVANSE 20 mg capsule (AUST R 284019): ivory opaque body and ivory opaque cap, printed 'S489' and '20 mg' in black ink.

VYVANSE 30 mg capsule (AUST R 199227): white opaque body and pink opaque cap, printed 'S489' and '30 mg' in black ink.

VYVANSE 40 mg capsule (AUST R 284020): white opaque body and blue/green opaque cap, printed 'S489' and '40 mg' in black ink.

VYVANSE 50 mg capsule (AUST R 199226): white opaque body and blue opaque cap, printed 'S489' and '50 mg' in black ink.

VYVANSE 60 mg capsule (AUST R 284021): aqua blue opaque body and aqua blue opaque cap, printed 'S489' and '60 mg' in black ink.

VYVANSE 70 mg capsule (AUST R 199228): 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.

Who distributes VYVANSE

Takeda Pharmaceuticals Australia Pty Ltd

Level 39

225 George Street

Sydney NSW 2000

Australia

Phone: 1800 012 612

www.takeda.com/en-au

This leaflet was prepared in February 2023.

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