DOSE AND ADMINISTRATION GUIDE

Vyvanse®
lisdexamfetamine dimesilate

VYVANSE® (lisdexamfetamine dimesilate)
Dose and administration guide[1]

Indications[1]

ADHD

- VYVANSE is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD)[1].
- Treatment should be commenced by a specialist as part of a comprehensive treatment program and re-evaluated periodically during long-term use.[1]

BED

- VYVANSE is indicated for the treatment of moderate to severe Binge Eating Disorder (BED) in adults when non-pharmacological treatment is unsuccessful or unavailable.[1]
- Treatment should be commenced and managed by a psychiatrist.[1]
- For BED the initial treatment period is 12 weeks. Patients should then be observed to assess whether further treatment with VYVANSE is required. Periodic re-evaluation of the usefulness of VYVANSE for the individual patient should be undertaken.[1]

Dose by indication[1]

ADHD

30 mg

When in the judgment of the clinician a lower initial dose is appropriate, patients may begin treatment with 20 mg once daily.

Adjust dose as required

(40 mg, 50 mg, 60 mg, 70 mg doses available)

Adjust daily dose in no more than 20 mg increments and no more frequently than weekly as necessary, based on clinical response until therapeutic dose is achieved.

70 mg

Maximum recommended daily dose.

Target ADHD dose range

BED

30 mg

Starting dose is not a therapeutic treatment dose.

After one week titrate to 50 mg.

Increase dose as required

(50 mg, 70 mg doses available)

Adjust daily dose in 20 mg increments - no more frequently than weekly as necessary, based on clinical response until therapeutic dose is achieved.

70 mg

Maximum recommended daily dose.

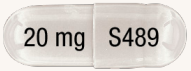
Target BED dose range

Adapted from VYVANSE® Approved Product Information[1]

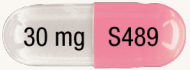
Dosing[1]

- Due to reduced clearance in patients with severe renal insufficiency (GFR 15 to < 30 mL/min/1.73 m^2) the maximum dose should not exceed 50 mg/day.
- Further dosage reduction should be considered in patients undergoing dialysis.

Range of VYVANSE doses available[1]

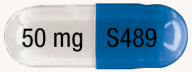


20 mg

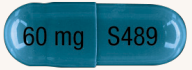


30 mg

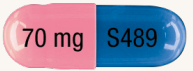
40 mg



50 mg



60 mg



70 mg

Capsules not actual size

VYVANSE Administration[1]

- Avoid afternoon doses because of the potential for insomnia.[1]
- Take once daily in the morning, with or without food.[1]

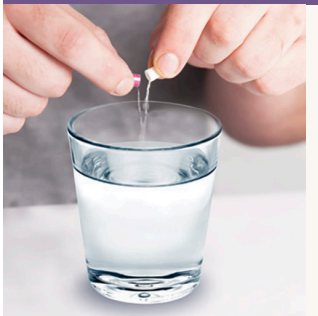
Vyvanse®
lisdexamfetamine dimesilate

How to take VYVANSE: Instructions for patients[1]

OPTION 1

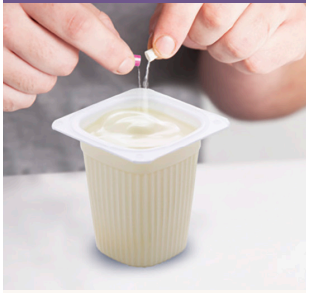
- Swallow the VYVANSE capsule whole, with or without food.

OPTION 2



1. Open the VYVANSE capsule and pour powder into a glass of water or orange juice. Use all the powder, so you get all the medicine.
2. Using a spoon, break apart any powder that is stuck together. Stir powder and water or orange juice until completely mixed together.
3. Drink entire glass after mixing. Do not store it. Don't worry if there is a film or residue left in the glass afterwards – this is not the active ingredient.

OPTION 3



- VYVANSE can also be mixed with yogurt. Consume all the yogurt right away.

(Please follow **options 2** or **3** if you prefer not to swallow a capsule)

Please review Product Information before prescribing. Product Information is available from Takeda Pharmaceuticals Australia Pty Ltd. Phone: 1800 012 612. Email: medinfoAPAC@takeda.com

For further information about the appropriate selection of patients and prescribing of VYVANSE, please visit http://www.ldxguide.com/au (password: onetakeda)

PBS Information: Authority required. Attention deficit hyperactivity disorder (ADHD).
Refer to PBS Schedule for full authority information.
This product is not listed on the PBS for the treatment of Binge Eating Disorder (BED).

VYVANSE has a potential for abuse, misuse, dependence, or diversion for non-therapeutic uses. Physicians should assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy. VYVANSE should be prescribed cautiously to patients with a history of substance abuse or dependence. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

Minimum Product Information. VYVANSE® (lisdexamfetamine dimesilate). Indication: Attention Deficit Hyperactivity Disorder (ADHD): Indicated for treatment of ADHD. Treatment should be commenced by a specialist as part of a comprehensive treatment program and re-evaluated periodically during long-term use. Binge Eating Disorder (BED): Indicated for treatment of moderate to severe BED in adults when non-pharmacological treatment is unsuccessful or unavailable. Treatment should be commenced and managed by a psychiatrist. **Dosage and Administration:** VYVANSE should be initiated at 30 mg once daily in the morning (avoid afternoon doses due to potential for insomnia) and slowly adjusted to the lowest effective dose (no more frequently than weekly). Capsules may be taken whole, or opened and the contents emptied and mixed with a soft food such as yogurt or in a glass of water or orange juice. **Contraindications:** Advanced arteriosclerosis; symptomatic cardiovascular disease (eg cardiac arrhythmia, ischaemic heart disease); moderate to severe hypertension; hyperthyroidism; hypersensitivity or idiosyncratic reaction to sympathomimetic amines or any of the excipients; glaucoma; agitated states (eg severe anxiety, tension and agitation); administration during or within 14 days of cessation of MAOIs; phaeochromocytoma; tics, Tourette's syndrome; patients who exhibit severe depression, anorexia nervosa, psychotic symptoms or suicidal tendency; drug dependence or alcohol abuse. **Precautions:** Cardiovascular disease; psychiatric disorders (psychosis, bipolar disease, aggression); seizures; visual disturbance; long-term suppression of growth, peripheral vasculopathy including Raynaud's phenomenon. Renal impairment (severe renal insufficiency max dose 50mg/day; dose reduction for dialysis patients). No data in hepatic impairment. Pregnancy: Category B3. Women taking VYVANSE should refrain from breast feeding. Not studied in children <6 years or adults >55 years of age. **Interactions:** MAOIs (see Contraindications), antihypertensives, narcotic analgesics, antipsychotics, agents that alter urinary pH, serotonergic drugs. **Adverse Effects:** Very Common reactions: decreased appetite, insomnia, headache, dry mouth, upper abdominal pain, weight decreased. Common reactions: anorexia, agitation, anxiety, libido decreased, tic, affect lability, psychomotor hyperactivity, bruxism, aggression, dizziness, restlessness, tremor, somnolence, mydriasis, tachycardia, palpitation, dyspnoea, diarrhoea, nausea, vomiting, hyperhidrosis, rash, irritability, fatigue, feeling jittery, pyrexia, blood pressure increased, erectile dysfunction. Note: where frequency of adverse reactions varies across age groups (children, adolescents, adults), the adverse reaction is listed according to the highest frequency. (pi-01047. V1.0)

Reference: 1. VYVANSE® (lisdexamfetamine dimesilate) Approved Product Information.

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