Vyvanse (lisdexamfetamine dimesylate) - Drug Summary

Shire LLC

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Vyvanse
(lisdexamfetamine dimesylate)

BOXED WARNING

CNS stimulants (amphetamines and methylphenidate-containing products) have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.

THERAPEUTIC CLASS

CNS stimulant

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

Attention-Deficit Hyperactivity Disorder

Initial: 30mg qam
Titrate: May adjust in increments of 10mg or 20mg at approx weekly intervals
Max: 70mg/day

Binge Eating Disorder

Moderate to Severe:
Initial: 30mg qam
Titrate: Titrate in increments of 20mg at approx weekly intervals
Target Dose: 50-70mg/day
Max: 70mg/day

PEDIATRIC DOSAGE & INDICATIONS

Attention-Deficit Hyperactivity Disorder

≥6 Years:
Initial: 30mg qam
Titrate: May adjust in increments of 10mg or 20mg at weekly intervals
Max: 70mg/day

DOSING CONSIDERATIONS

Renal Impairment
Severe (GFR 15-<30mL/min/1.73m^2):
Max: 50mg/day

ESRD (GFR <15mL/min/1.73m^2):
Max: 30mg/day

Elderly
Start at lower end of dosing range

ADMINISTRATION

Oral route

Take in am w/ or w/o food; avoid afternoon doses

May swallow caps whole
Do not take anything less than 1 cap/day; do not divide a single cap

Open Caps
1. May open caps, empty, and mix entire contents w/ yogurt, water, or orange juice; if contents of cap include any compacted powder, may use a spoon to break apart the powder
2. Mix contents until completely dispersed
3. Immediately consume entire mixture; do not store
Film containing inactive ingredients may remain in glass/container once mixture is consumed

HOW SUPPLIED

Cap: 10mg, 20mg, 30mg, 40mg, 50mg, 60mg, 70mg

CONTRAINDICATIONS

Concurrent use w/ an MAOI or use w/in 14 days of the last MAOI dose.

WARNINGS/PRECAUTIONS

Not indicated or recommended for weight loss. Sudden death, stroke, and MI reported in adults. Sudden death reported in children and adolescents w/ structural cardiac abnormalities and other serious heart problems. Avoid use in patients w/ known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, and other serious heart problems. May cause increase in BP and HR. May exacerbate symptoms of behavior disturbance and thought disorder in patients w/ a preexisting psychotic disorder. May induce a mixed/manic episode in patients w/ bipolar disorder. May cause psychotic or manic symptoms (eg, hallucinations, delusional thinking, mania) in children and adolescents w/o a prior history of psychotic illness or mania; consider discontinuation if symptoms occur. Associated w/ weight loss and slowing of growth rate in pediatric patients. Associated w/ peripheral vasculopathy, including Raynaud's phenomenon; further clinical evaluation (eg, rheumatology referral) may be appropriate for certain patients.

ADVERSE REACTIONS

Decreased appetite, insomnia, upper abdominal pain, irritability, N/V, decreased weight, dry mouth, dizziness, constipation, rash, diarrhea, anxiety, anorexia, jittery feeling, increased HR.

DRUG INTERACTIONS

See Contraindications. Urinary acidifying agents (eg, ascorbic acid) increase urinary excretion and decrease the $T_{1/2}$ of amphetamine, while urinary alkalinizing agents (eg, sodium bicarbonate) decrease urinary excretion and extend the $T_{1/2}$ of amphetamine; adjust dose accordingly.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Sympathomimetic amine; CNS stimulant. Prodrug of dextroamphetamine. Blocks the reuptake of norepinephrine and dopamine into the presynaptic neuron and increases the release of these monoamines into the extraneuronal space.

PHARMACOKINETICS

Absorption: Rapid; T_{max}=1 hr (lisdexamfetamine), 3.5 hrs (dextroamphetamine). **Distribution:** Found in breast milk. **Metabolism:** Hydrolysis by RBCs; dextroamphetamine (active metabolite). **Elimination:** Urine (96%; 42% amphetamine, 25% hippuric acid, 2% unchanged), feces (0.3%); $T_{1/2}$=<1 hr.

ASSESSMENT

Assess for presence of cardiac disease, risk of abuse, risk factors for developing a manic episode, psychosis, bipolar disorder, hypersensitivity to the drug or amphetamine products, renal impairment, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for potential tachycardia, HTN, exacerbation of preexisting psychosis, psychotic or manic symptoms in children and adolescents, and other adverse reactions. Monitor height and weight in pediatric patients. Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias. Observe carefully for signs/symptoms of peripheral vasculopathy (eg, digital changes). Monitor for signs of abuse and dependence; periodically reevaluate the need for therapy.

PATIENT COUNSELING

Inform about drug abuse/dependence risk. Advise about serious cardiovascular risks; instruct to contact physician immediately if symptoms of cardiac disease develop. Instruct to monitor for elevations of BP and pulse rate. Inform that psychotic or manic symptoms may occur. Instruct parents or caregivers of pediatric patients that therapy may cause slowing of growth, including weight loss. Inform that therapy may impair ability to engage in potentially dangerous activities (eg, operating machinery); instruct patients to assess how the medication affects them before engaging in potentially dangerous activities. Inform about the risk of peripheral vasculopathy, including Raynaud's phenomenon; instruct to report to physician any new numbness, pain, skin color change, or sensitivity to temperature in fingers or toes, and to call physician immediately if any signs of unexplained wounds appear on fingers or toes while on therapy.

STORAGE

20-25°C (68-77°F); excursions permitted between 15-30°C (59-86°F).

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