Dexedrine (dextroamphetamine sulfate) - Drug Summary

Amedra Phramaceuticals LLC

Jump to Section
BOXED WARNING
THERAPEUTIC CLASS
DEA CLASS
ADULT DOSAGE & INDICATIONS
PEDIATRIC DOSAGE & INDICATIONS
▼ View All Sections...

Related Drug Information ▼

Dexedrine Spansule
(dextroamphetamine sulfate)

BOXED WARNING

High potential for abuse. Prolonged use may lead to drug dependence and must be avoided. Misuse may cause sudden death and serious cardiovascular (CV) adverse events.

THERAPEUTIC CLASS

CNS stimulant

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

Narcolepsy

Individualize dose and administer at the lowest effective dose

Initial: 10mg/day
Titrate: May increase daily dose in increments of 10mg at weekly intervals until optimal response is obtained
Usual: 5-60mg/day in divided doses

PEDIATRIC DOSAGE & INDICATIONS

Narcolepsy

Individualize dose and administer at the lowest effective dose

Usual: 5-60mg/day in divided doses

6-12 Years:
Initial: 5mg/day
Titrate: May increase daily dose in increments of 5mg at weekly intervals until optimal response is obtained

≥12 Years:
Initial: 10mg/day
Titrate: May increase daily dose in increments of 10mg at weekly intervals until optimal response is obtained

Attention-Deficit Hyperactivity Disorder

Individualize dose and administer at the lowest effective dose

≥6 Years:
Initial: 5mg qd or bid
Titrate: May increase daily dose in increments of 5mg at weekly intervals until optimal response is obtained

Only rarely will it be necessary to exceed 40mg/day

DOSING CONSIDERATIONS

Adverse Reactions
Narcolepsy:
Reduce dose if bothersome adverse reactions appear (eg, insomnia or anorexia)

ADMINISTRATION

Oral route

Avoid late pm doses
May be used for once-a-day dosage wherever appropriate

HOW SUPPLIED

Cap, Sustained-Release: 5mg, 10mg, 15mg

CONTRAINDICATIONS

Advanced arteriosclerosis, symptomatic CV disease (CVD), moderate to severe HTN, hyperthyroidism, glaucoma, agitated states, and history of drug abuse. During or w/in 14 days following MAOI use.

WARNINGS/PRECAUTIONS

Avoid w/ known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac problems. Sudden death reported in children and adolescents w/ structural cardiac abnormalities or other serious heart problems. Sudden death, stroke, and MI reported in adults. May cause a modest increase in average BP and HR. Promptly perform cardiac evaluation if symptoms suggestive of cardiac disease develop during treatment. May exacerbate symptoms of behavior disturbance and thought disorder in patients w/ preexisting psychotic disorder. Caution w/ comorbid bipolar disorder; may induce mixed/manic episode. May cause treatment-emergent psychotic or manic symptoms in children and adolescents w/o a prior history of psychotic illness or mania; consider discontinuation if such symptoms occur. Aggressive behavior or hostility reported in children and adolescents w/ ADHD. May cause long-term suppression of growth in children. May lower convulsive threshold; d/c if seizures occur. Associated w/ peripheral vasculopathy, including Raynaud's phenomenon. Difficulties w/ accommodation and blurring of vision reported. May exacerbate motor and phonic tics, and Tourette's syndrome. May significantly elevate plasma corticosteroid levels and interfere w/ urinary steroid determinations. In patients w/ ADHD, where possible, interrupt administration occasionally to determine if there is a recurrence of behavioral symptoms sufficient to require continued therapy.

ADVERSE REACTIONS

Palpitations, tachycardia, BP elevation, dizziness, insomnia, euphoria, dyskinesia, headache, dryness of mouth, diarrhea, constipation, urticaria, impotence, changes in libido, rhabdomyolysis.

DRUG INTERACTIONS

See Contraindications. GI acidifying agents (eg, guanethidine, reserpine, glutamic acid HCl) and urinary acidifying agents (eg, ammonium chloride, sodium acid phosphate) lower blood levels and efficacy. Inhibits adrenergic blockers. GI alkalinizing agents (eg, sodium bicarbonate) and urinary alkalinizing agents (eg, acetazolamide, some thiazides) increase blood levels and therefore potentiate actions. May enhance activity of TCAs or sympathomimetic agents. Desipramine or protriptyline and possibly other TCAs cause striking and sustained increases in the concentration of *d*-amphetamine in the brain; CV effects can be potentiated. May counteract sedative effect of antihistamines. May antagonize hypotensive effects of antihypertensives. Chlorpromazine and haloperidol inhibit central stimulant effects. May delay intestinal absorption of ethosuximide, phenobarbital, and phenytoin; coadministration w/ phenobarbital or phenytoin may produce a synergistic anticonvulsant action. Lithium carbonate may inhibit stimulatory effects. Potentiates analgesic effect of meperidine. Acidifying agents used in methenamine therapy increase urinary excretion and reduce efficacy. Enhances adrenergic effect of norepinephrine. In cases of propoxyphene overdosage, CNS stimulation is potentiated and fatal convulsions can occur. Inhibits hypotensive effect of veratrum alkaloids.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Sympathomimetic amine; not established. Has CNS stimulant activity.

PHARMACOKINETICS

Absorption: (15mg cap) C_{max}=23.5ng/mL; T_{max}=8 hrs. **Distribution:** Found in breast milk. **Elimination:** $T_{1/2}$=12 hrs.

ASSESSMENT

Assess for hypersensitivity/idiosyncrasy to sympathomimetic amines, advanced arteriosclerosis, symptomatic CVD, moderate to severe HTN, hyperthyroidism, glaucoma, agitated states, history of drug abuse, tics, Tourette's syndrome, preexisting psychotic disorder, risk for/comorbid bipolar disorder, cardiac disease, medical conditions that might be compromised by increases in BP or HR, family history of sudden death or ventricular arrhythmia, any other conditions where treatment is cautioned, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for changes in HR and BP, signs/symptoms of cardiac disease, exacerbation of behavioral disturbance and thought disorder, psychosis, mania, appearance of or worsening of aggressive behavior or hostility, seizures, peripheral vasculopathy, visual disturbances, exacerbation of motor and phonic tics or Tourette's syndrome, and other adverse reactions. In pediatric patients, monitor growth.

PATIENT COUNSELING

Inform about benefits and risks of treatment and counsel about appropriate use. Counsel that drug has high potential for abuse. Caution against engaging in potentially hazardous activities (eg, operating machinery/vehicles). Instruct to report to physician any new numbness, pain, skin color change, or sensitivity to temperature in fingers or toes, and to contact physician immediately w/ any signs of unexplained wounds

appearing on fingers or toes while taking the drug.

STORAGE

20-25°C (68-77°F).

Back to top