Desoxyn (methamphetamine hydrochloride) - Drug Summary

Recordati Rare Diseases, Inc.

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Desoxyn (methamphetamine hydrochloride)

BOXED WARNING

High potential for abuse; should be tried only in weight reduction programs for patients in whom alternative therapy has been ineffective. Prolonged use in obesity may lead to drug dependence and must be avoided. Misuse may cause sudden death and serious cardiovascular adverse events.

THERAPEUTIC CLASS

CNS stimulant

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

Obesity

Management of exogenous obesity as a short-term (few weeks) adjunct in a regimen of weight reduction based on caloric restriction, for patients in whom obesity is refractory to alternative therapy

Usual: 5mg, taken 30 min before each meal

PEDIATRIC DOSAGE & INDICATIONS

Attention-Deficit Hyperactivity Disorder

≥6 Years:
Initial: 5mg qd or bid
Titrate: May increase daily dose in increments of 5mg at weekly intervals until an optimum clinical response is achieved
Usual: 20-25mg/day

Total daily dose may be given in 2 divided doses

Where possible, interrupt administration occasionally to determine if there is a recurrence of behavioral symptoms sufficient to require continued therapy

Obesity

Management of exogenous obesity as a short-term (few weeks) adjunct in a regimen of weight reduction based on caloric restriction, for patients in whom obesity is refractory to alternative therapy

≥12 Years:
Usual: 5mg, taken 30 min before each meal

DOSING CONSIDERATIONS

Elderly
Start at lower end of dosing range

ADMINISTRATION

Oral route

Avoid late pm administration

HOW SUPPLIED

Tab: 5mg

CONTRAINDICATIONS

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

WARNINGS/PRECAUTIONS

Tolerance to anorectic effect usually develops w/in a few weeks; d/c therapy. Do not use to combat fatigue or replace rest. 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 deaths, stroke, and MI reported in adults at ADHD doses. May cause a modest increase in average BP and HR; caution w/ conditions that might be compromised by increases in BP/HR. Promptly perform cardiac evaluation if symptoms suggestive of cardiac disease develop. May exacerbate symptoms of behavior disturbance and thought disorder in patients w/ preexisting psychotic disorder. Caution in patients w/ comorbid bipolar disorder; may induce mixed/manic episodes. May cause treatment-emergent psychotic or manic symptoms (eg, hallucinations, delusional thinking, mania) in children and adolescents w/o 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; monitor growth. Treatment may need to be interrupted in patients not growing or gaining height or weight as expected. May lower convulsive threshold; d/c if seizures occur. Associated w/ peripheral vasculopathy, including Raynaud's phenomenon; carefully observe for digital changes. Difficulties w/ accommodation and blurring of vision reported. May exacerbate motor and phonic tics and Tourette's syndrome; evaluate for history of these conditions prior to therapy. May elevate plasma corticosteroid levels.

ADVERSE REACTIONS

BP elevation, tachycardia, palpitation, dizziness, dysphoria, overstimulation, euphoria, insomnia, diarrhea, constipation, dryness of mouth, urticaria, impotence, changes in libido, rhabdomyolysis.

DRUG INTERACTIONS

See Contraindications. May alter insulin requirements. May decrease hypotensive effect of guanethidine. Caution w/ TCAs. Phenothiazines may antagonize CNS stimulant action.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Sympathomimetic amine; not established. CNS stimulant and anorectic/anorexigenic. May suppress appetite.

PHARMACOKINETICS

Absorption: Rapid. **Distribution:** Found in breast milk. **Metabolism:** Liver, by aromatic hydroxylation, N-dealkylation, and deamination. **Elimination:** Urine (approx 62% w/in 1st 24 hrs; 1/3 unchanged); $T_{1/2}$=4-5 hrs.

ASSESSMENT

Assess for hypersensitivity/idiosyncrasy to sympathomimetic amines, glaucoma, advanced arteriosclerosis, symptomatic CVD, moderate to severe HTN, hyperthyroidism, agitated states, history of drug abuse, tics, Tourette's syndrome, preexisting psychotic disorder, any other conditions where treatment is cautioned or contraindicated, pregnancy/nursing status, and possible drug interactions. Perform careful medical history and physical exam to assess for presence of cardiac disease. Adequately screen patients w/ comorbid depressive symptoms to determine risk for bipolar disorder.

MONITORING

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

PATIENT COUNSELING

Inform about risks and benefits of treatment and counsel about appropriate use. Inform about impairment in ability to engage 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. Instruct not to increase dosage, except on advice of the physician.

STORAGE

<30°C (86°F).

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