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Didrex (benzphetamine hydrochloride) - Drug Summary

Pharmacia and Upjohn Company

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Didrex (benzphetamine hydrochloride)

THERAPEUTIC CLASS

Anorectic sympathomimetic amine

DEA CLASS

CIII

ADULT DOSAGE & INDICATIONS

Obesity

Short-term (few weeks) adjunctive therapy in weight reduction regimen based on caloric restriction in the management of exogenous obesity in patients with initial BMI ≥30kg/m^2

Initial: 25-50mg qd
Usual: 25-50mg qd-tid

PEDIATRIC DOSAGE & INDICATIONS

Obesity

Short-term (few weeks) adjunctive therapy in weight reduction regimen based on caloric restriction in the management of exogenous obesity in patients with initial BMI ≥30kg/m^2

≥12 Years:
Initial: 25-50mg qd
Usual: 25-50mg qd-tid

DOSING CONSIDERATIONS

Elderly
Start at the lower end of dosing range

ADMINISTRATION

Oral route

Single daily dose is preferably given in mid-morning or mid-afternoon, according to eating habits
Avoid late afternoon administration in certain patients

HOW SUPPLIED

Tab: 50mg* *scored

CONTRAINDICATIONS

Advanced arteriosclerosis, symptomatic cardiovascular (CV) disease, moderate to severe HTN, agitated states, hyperthyroidism, glaucoma, history of drug abuse, concomitant CNS stimulant use, MAOI use concomitantly or within 14 days, pregnancy.

WARNINGS/PRECAUTIONS

May increase the risk of pulmonary HTN if used >3 months; d/c and evaluate for possible pulmonary HTN if exertional dyspnea, or unexplained angina pectoris, syncope, or lower extremity edema occur. Prolonged use or higher than recommended doses may contribute to the development of valvular heart disease; perform ECG during and after therapy to detect valvular disorders. Consider baseline cardiac evaluation should to detect pre-existing valvular heart diseases or pulmonary HTN prior to therapy. To limit unwarranted exposure and risks,

continue treatment only if satisfactory weight loss occurs within the 1st 4 weeks of treatment. D/C if tolerance develops. Psychological disturbances reported with restrictive dietary regimen. Not recommended with heart murmur/valvular heart disease, severe HTN, symptomatic CV disease including arrhythmias, and those who used any anorectic agents within the prior year. Caution with mild HTN and in elderly. Not recommended in children <12 yrs.

ADVERSE REACTIONS

Palpitation, tachycardia, BP elevation, restlessness, dizziness, insomnia, headache, tremor, sweating, dry mouth, nausea, diarrhea, unpleasant taste, urticaria, altered libido.

DRUG INTERACTIONS

See Contraindications. Hypertensive crisis risk if used concomitantly or within 14 days of MAOIs. May potentiate TCAs. Avoid with other CNS stimulants. May decrease hypotensive effects of antihypertensives. Increased blood levels and decreased excretion of amphetamines when taken with urinary alkalinizing agents. Decreased blood levels and increased excretion of amphetamines when taken with urinary acidifying agents. May alter insulin requirements in diabetes mellitus (DM). Avoid with other anorectic agents (including prescribed, OTC, and herbal products). Use in combination with other anorectic drugs such as fenfluramine and dexfenfluramine may lead to valvular heart disease.

PREGNANCY AND LACTATION

Category X, not for use in nursing.

MECHANISM OF ACTION

Anorectic sympathomimetic amine; not established as appetite suppressor; CNS stimulant.

PHARMACOKINETICS

Distribution: Found in breast milk.

ASSESSMENT

Assess for DM, advanced arteriosclerosis, symptomatic CV disease including arrhythmias, HTN, glaucoma, hyperthyroidism, agitated states, history of drug abuse, hypersensitivity or idiosyncrasy to sympathomimetic amines, pre-existing valvular heart disease or pulmonary HTN, patients with known heart murmur, use of any anorectic agents within the prior year, pregnancy/nursing status, and possible drug interactions. Perform baseline cardiac evaluation prior to treatment. Assess risk of serious adverse effects (eg, valvular heart disease/pulmonary HTN) against potential weight loss benefit.

MONITORING

Obtain baseline vital signs and weight. Monitor for weight loss and continue treatment only if satisfactory weight loss occurs within the 1st 4 weeks. Monitor for signs/symptoms of HTN, psychological disturbances, hypersensitivity reactions, and for tolerance. Monitor for valvular heart disease and pulmonary HTN (eg, exertional dyspnea, angina pectoris, syncope, lower extremity edema). Perform ECG during and after treatment.

PATIENT COUNSELING

Advise patients on possible impairment of physical abilities; caution should be used when engaging in potentially hazardous activities. Caution that tolerance may develop; do not exceed recommended dosage, rather d/c therapy. Advise to seek medical attention if symptoms of hypersensitivity reactions or HTN occur. Counsel to avoid if patient is pregnant or may become pregnant due to fetal harm. May be desirable to avoid late afternoon administration.

STORAGE

20-25°C (68-77°F).

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