Phendimetrazine Tartrate Extended-Release Capsules (phendimetrazine tartrate) - Drug Summary

Eon labs, Inc.

Jump to Section
COMMON BRAND NAMES
THERAPEUTIC CLASS
DEA CLASS
ADULT DOSAGE & INDICATIONS
DOSING CONSIDERATIONS
▼ View All Sections...

Related Drug Information ▼

Phendimetrazine ER (phendimetrazine tartrate)

COMMON BRAND NAMES

Bontril (Discontinued), Phendimetrazine ER

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 or ≥27kg/m^2 in the presence of other risk factors (eg, controlled HTN, diabetes, hyperlipidemia)

≥17 Years:
1 cap (105mg) qam

DOSING CONSIDERATIONS

Elderly
Start at lower end of dosing range

ADMINISTRATION

Oral route

Administer 30-60 min before morning meal

HOW SUPPLIED

Cap, Extended-Release: 105mg

CONTRAINDICATIONS

History of cardiovascular disease (CVD) [eg, coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled HTN, pulmonary HTN], hyperthyroidism, glaucoma, agitated states, history of drug abuse, pregnancy, nursing, during or within 14 days following administration of MAOIs, use in combination with other anorectic agents or CNS stimulants.

WARNINGS/PRECAUTIONS

Use as monotherapy only. May increase risk of developing pulmonary HTN; d/c immediately if onset/aggravation of exertional dyspnea, unexplained symptoms of angina pectoris, syncope, or lower extremity edema occur. Valvular heart disease (VHD) may occur; not recommended with known heart murmur or VHD.

Carefully assess potential risk of possible serious adverse effects (eg, VHD, pulmonary HTN) against potential benefit of weight loss. Perform baseline cardiac evaluation prior to initiation of therapy, and ECG during and after treatment. Tolerance to anorectic effect develops within a few weeks; do not exceed recommended dose if this occurs, rather d/c therapy. Fatigue and depression may occur with abrupt cessation after prolonged high dose therapy. May impair mental/physical abilities. Not recommended in patients who used any anorectic agents within the prior year. Least amount feasible should be prescribed/dispensed at one time to minimize possibility of overdosage. Caution with HTN (even if mild), renal impairment, and in elderly.

ADVERSE REACTIONS

Primary pulmonary HTN and/or regurgitant cardiac valvular disease, palpitation, tachycardia, BP elevation, ischemic events, overstimulation, restlessness, insomnia, agitation, dry mouth, nausea, stomach pain, diarrhea, urinary frequency, dysuria, libido changes.

DRUG INTERACTIONS

See Contraindications. Concomitant use of alcohol may result in an adverse reaction. May alter insulin and oral hypoglycemic drug requirements in diabetes mellitus patients. May decrease hypotensive effects of guanethidine and adrenergic neuron blocking drugs.

PREGNANCY AND LACTATION

Category X, not for use in nursing.

MECHANISM OF ACTION

Anorectic sympathomimetic amine; has not been established. Suspected to cause appetite suppression.

PHARMACOKINETICS

Metabolism: Phenmetrazine, phendimetrazine-N-oxide (metabolites). **Elimination:** Kidney (major). $T_{1/2}$=3.7 (controlled conditions).

ASSESSMENT

Assess for hypersensitivity or idiosyncratic reactions to sympathomimetics, history of CVD, hyperthyroidism, glaucoma, agitated states, history of drug abuse, VHD, pulmonary HTN, heart murmur, pregnancy/nursing status, and possible drug interactions. Perform baseline cardiac evaluation prior to initiation.

MONITORING

Perform ECG during and after therapy. Monitor weight, drug tolerance, signs/symptoms of pulmonary HTN, hypersensitivity reactions, VHD, HTN, and other adverse reactions.

PATIENT COUNSELING

Inform of potential benefits/risks of therapy. Instruct to take caution in driving/operating machinery. Advise to seek medical attention if symptoms of pulmonary HTN, hypersensitivity reactions, or HTN occur. Instruct not to use in combination with other anorectic agents, including prescribed drugs, OTC, and herbal products. Instruct to take exactly ud; inform about the potential for developing tolerance and risk of dependence.

STORAGE

20-25°C (68-77°F). Protect from moisture.

Back to top