BENACOLD-DX™

BENACOLD-DX™
Dextromethorphan Hydrobromide 10 mg/ Chlorpheniramine Maleate 2mg,
Menthol 1mg. / Phenylpropanolamine Hydrochloride 12.5 mg.

TAJ PHARMACEUTICALS LIMITED

"Working for healthier India"

Category
Decongestant, nasal (systemic)—
Indications
Congestion, nasal (treatment), Congestion, sinus (treatment) or Congestion, eustachian tube (treatment)—Pseudoephedrine is indicated for temporary relief of congestion associated with acute coryza, acute eustachian salpingitis, serous otitis media with eustachian tube congestion, vasomotor rhinitis , and aerotitis (barotitis) media. Pseudoephedrine also may be indicated as an adjunct to analgesics, antihistamines, antibiotics, antitussives, or expectorants for optimum results in allergic rhinitis , croup, acute and subacute sinusitis, acute otitis media, and acute tracheobronchitis.

Mechanism of action
Pseudoephedrine acts on alpha-adrenergic receptors in the mucosa of the respiratory tract, producing vasoconstriction. The medication shrinks swollen nasal mucous membranes; reduces tissue hyperemia, edema, and nasal congestion; and increases nasal airway patency. Also, drainage of sinus secretions may be increased and obstructed eustachian ostia may be opened.

Biotransformation
Pseudoephedrine is incompletely metabolized in the liver.

Onset of action
15 to 30 minutes.

Time to peak effect
Within 30 to 60 minutes.

Duration of action
Tablets, oral solution, and syrup—3 to 4 hours.
Extended-release capsules and tablets—8 to 12 hours.

Elimination
Renal. About 55 to 75% of a dose is excreted unchanged. The rate of excretion is accelerated in acidic urine.

Precautions to Consider
Patients sensitive to other sympathomimetics (for example, albuterol, amphetamines, ephedrine, epinephrine, isoproterenol, metaproterenol, norepinephrine, phenylephrine, phenylpropanolamine, terbutaline) may be sensitive to this medication also.

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Pregnancy/Reproduction

Pregnancy—

Studies in humans have not been done.

Studies in animals have not shown that pseudoephedrine causes teratogenic effects in the fetus. However, pseudoephedrine reduced average weight, length, and rate of skeletal ossification in the animal fetus.

Breast-feeding

Pseudoephedrine is distributed into breast milk; use by nursing mothers is not recommended, because of the higher than usual risk to infants, especially newborn and premature infants, of side effects from sympathomimetic amines. {32}

Pediatrics

Pseudoephedrine should be used with caution in infants, especially newborn and premature infants, because of the higher than usual risk of side/adverse effects.

Geriatrics

No information is available on the relationship of age to the effects of pseudoephedrine in geriatric patients. However, elderly patients are more likely to have age-related prostatic hypertrophy, which may require adjustment of dosage in patients receiving pseudoephedrine.

Drug interactions and/or related problems

The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance (possible mechanism in parentheses where appropriate)—not necessarily inclusive (» = major clinical significance):

Note: Combinations containing any of the following medications, depending on the amount present, may also interact with this medication.

Anesthetics, hydrocarbon inhalation, such as:

Chloroform
Cyclopropane
Enflurane
Halothane
Isoflurane
Methoxyflurane
Trichloroethylene (administration of pseudoephedrine prior to or shortly after anesthesia with chloroform, cyclopropane, halothane, or trichloroethylene may increase the risk of severe ventricular arrhythmias, especially in patients with pre-existing heart disease, because these anesthetics greatly sensitize the myocardium to the effects of sympathomimetics)

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(enflurane, isoflurane, or methoxyflurane may also cause some sensitization of the myocardium to the effects of sympathomimetics; caution is recommended in patients taking pseudoephedrine)

Antihypertensives or Diuretics used as antihypertensives (antihypertensive effects may be reduced when these medications are used concurrently with pseudoephedrine; the patient should be monitored carefully to confirm that the desired effect is being obtained

Beta-adrenergic blocking agents (concurrent use with pseudoephedrine may inhibit the therapeutic effect of these medications; beta-blockade may result in unopposed alpha-adrenergic activity of pseudoephedrine, with a risk of hypertension and excessive bradycardia and possible heart block

Central nervous system (CNS) stimulation–producing medications, other (concurrent use with pseudoephedrine may result in additive CNS stimulation to excessive levels, which may cause unwanted effects such as nervousness, irritability, insomnia, or possibly convulsions or cardiac arrhythmias; close observation is recommended)

Citrates (concurrent use may inhibit urinary excretion and prolong the duration of action of pseudoephedrine)

Cocaine, mucosal-local (in addition to increasing CNS stimulation, concurrent use with pseudoephedrine may increase the cardiovascular effects of either or both medications and the risk of adverse effects

Digitalis glycosides (concurrent use with pseudoephedrine may increase the risk of cardiac arrhythmias; caution and electrocardiographic monitoring are very important if concurrent use is necessary)

Levodopa (concurrent use with pseudoephedrine may increase the possibility of cardiac arrhythmias; dosage reduction of the sympathomimetic is recommended)

Monoamine oxidase (MAO) inhibitors, including furazolidone, procarbazine, and selegiline (concurrent use may prolong and intensify the cardiac stimulant and vasopressor effects of pseudoephedrine because of release of catecholamines, which accumulate in intraneuronal storage sites during MAO inhibitor therapy, resulting in headache, cardiac arrhythmias, vomiting, or sudden and severe hypertensive and/or hyperpyretic crises; pseudoephedrine should not be administered during or within 14 days following administration of MAO inhibitors.

Nitrates (concurrent use with pseudoephedrine may reduce the antianginal effects of these medications.

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Rauwolfia alkaloids (concurrent use may inhibit the action of pseudoephedrine by depleting catecholamine stores.

Sympathomimetics, other (in addition to possibly increasing CNS stimulation, concurrent use may increase the cardiovascular effects of either the other sympathomimetics or pseudoephedrine and the potential for side effects.

Thyroid hormones (concurrent use may increase the effects of either these medications or pseudoephedrine; thyroid hormones enhance risk of coronary insufficiency when sympathomimetic agents are administered to patients with coronary artery disease; dosage adjustment is recommended, although problem is reduced in euthyroid patients)

Medical considerations/Contraindications

The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate)— not necessarily inclusive (» = major clinical significance).

Presentation

Benacold-DX Syrup 100 ml Bottle

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.

Information for Health Care Professionals

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