

ALLERX-D

TABLETSTM
120 mg pseudoephedrine HCl and
2.5 mg methscopolamine nitrate

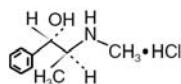
DESCRIPTION

Each tablet contains:

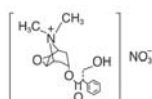
Pseudoephedrine HCL.....120 mg

Methscopolamine Nitrate.....2.5 mg

Pseudoephedrine hydrochloride is a nasal decongestant. Chemically it is [S-(R*,R*)]- α -[1(methylamino) ethyl]-benzenemethanol hydrochloride; C₁₀H₁₅NO•HCl, MW = 201.7.



Methscopolamine nitrate is an anticholinergic having the chemical name 3-oxa-9-azoniatricyclo [3.3.1.0^{2,4}] nonane, 7-(3-hydroxy-1-oxo-2-phenylpropoxy)-9, 9-dimethyl-, nitrate, [7(S)-(1 α , 2 β , 4 β , 5 α , 7 β)]; C₁₇H₂₁NO₄•CH₃NO₃, MW = 80.4.



Inactive Ingredients: Dibasic Calcium Phosphate, D & C Yellow #10 (aluminum lake) Dye, Magnesium Stearate, Methylcellulose, Povidone and Stearic Acid.

CLINICAL PHARMACOLOGY

Pseudoephedrine HCl is an indirect-acting sympathomimetic amine that exerts a decongestant action on the nasal mucosa. It does this by vasoconstriction, which results in reduction of tissue hyperemia, edema, nasal congestion, and an increase in nasal airway patency. In the usual dose it has minimal vasopressor effects. Pseudoephedrine HCl is rapidly and almost completely absorbed from the gastrointestinal tract. It has a plasma half-life of 6 to 8 hours. Alkaline urine is associated with slower elimination of the drug. The drug is distributed to the body tissues and fluids, including the central nervous system (CNS). Approximately 50% to 75% of the administered dose is excreted unchanged in the urine; the remainder is apparently metabolized in the liver to inactive compounds by N-demethylation, parahydroxylation, and oxidative deamination.

Methscopolamine nitrate is a quaternary ammonium derivative of the anticholinergic scopolamine which possesses the peripheral actions of the belladonna alkaloids, but does not exhibit the central actions because of its lack of ability to cross the blood-brain barrier. Its antimuscarinic effect causes inhibition of salivary secretions, reduction in volume and total acid content of gastric secretion, and inhibition of gastrointestinal motility. It is poorly and unreliably absorbed. Drug effects appear in about one hour and persist for about 4 to 6 hours. It is excreted primarily in the urine and bile, or as unabsorbed drug in feces.

INDICATIONS AND USAGE

For the temporary relief of symptoms associated with allergic rhinitis.

CONTRAINDICATIONS

This product is contraindicated in patients with hypersensitivity to pseudoephedrine HCl and methscopolamine nitrate. AlleRxTM-D is contraindicated in patients with severe hypertension, severe coronary artery disease, patients on monoamine oxidase inhibitor (MAOI) therapy or within 14 days of stopping monoamine oxidase inhibitor (MAOI) therapy. AlleRxTM-D is also contraindicated in patients with narrow-angle glaucoma, urinary retention, peptic ulcer, and during an asthmatic attack.

WARNINGS

Sympathomimetic amines should be used cautiously in patients with hypertension, diabetes mellitus, ischemic heart disease, hyperthyroidism, increased intraocular pressure, and prostatic hypertrophy. Sympathomimetics may produce central nervous system stimulation with convulsions or cardiovascular collapse with accompanying hypotension. The elderly (60 years or older) are more likely to exhibit adverse reactions. At dosages higher than the recommended dose, nervousness, dizziness, or sleeplessness may occur. Do not exceed recommended dosage.

Hypertensive crisis can occur with concurrent use of pseudoephedrine HCl and MAOI, and for 14 days after stopping MAOI therapy. Methscopolamine nitrate may produce drowsiness or blurred vision. The patient should be cautioned regarding activities requiring mental alertness such as operating a motor vehicle or performing hazardous work while taking AlleRxTM-D.

Co-administration of sildenafil citrate and other organic nitrates has been shown to potentiate the hypotensive effects of nitrates. Co-administration of AlleRxTM-D and sildenafil citrate has not been studied. Therefore, the use of sildenafil citrate and AlleRxTM-D together is not recommended.

PRECAUTIONS

General: AlleRxTM-D should be used with caution in patients with diabetes mellitus, hypertension, cardiovascular disease, and hyperactivity to sympathomimetic amines. Methscopolamine nitrate should be used with caution in the elderly and all patients with autonomic neuropathy, hepatic or renal disease, or ulcerative colitis.

Drug Interactions: Do not prescribe AlleRxTM-D for use in patients that are now taking prescription MAOIs (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 14 days after stopping MAOI drug therapy. Beta-adrenergic blockers and MAOIs may potentiate the pressor effect of pseudoephedrine HCl. Concurrent use of digitalis glycosides may increase the possibility of cardiac arrhythmias. Sympathomimetics may reduce the hypotensive effects of guanethidine, mecamlamine, methyl dopa, reserpine and veratrum alkaloids. Concurrent use of pseudoephedrine HCl with

other sympathomimetic amines may increase pressor or cardiovascular effects of either medication.

The use of pseudoephedrine HCl may result in additive CNS depressant effects when coadministered with alcohol, antihistamines, psychotropics, or other drugs which produce CNS depression. Concurrent use of tricyclic antidepressants may antagonize the effects of pseudoephedrine HCl.

Additive anticholinergic effects may result from concomitant use with antipsychotics, tricyclic antidepressants, and other drugs with anticholinergic effects. Concomitant administration with antacids may interfere with the absorption of methscopolamine nitrate.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Animal studies to assess the long-term carcinogenic and mutagenic potential or the effect on fertility in animals or humans have not been performed.

Pregnancy Category C: It is not known whether AlleRx™-D can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. AlleRx™-D should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether this combination drug is excreted in human milk. However, pseudoephedrine HCl administered alone distributes into the breast milk of lactating human females; therefore, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: The safety and effectiveness in children under 12 years of age have not been established.

Geriatric Use: The elderly (60 years and older) are more likely to experience adverse reactions to sympathomimetics. Overdosage of sympathomimetics in this age group may cause hallucinations, convulsions, CNS depression, and/or death. Pseudoephedrine HCl is known to be substantially excreted by the kidneys, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

Adverse reactions include drowsiness, lassitude, nausea, giddiness, dryness of mouth, blurred vision, cardiac palpitations, flushing, and increased irritability or excitement (especially in children). Some individuals may display sympathomimetic amine effects such as tachycardia, palpitations, headache, dizziness, or nausea. Sympathomimetics have been associated with certain untoward reactions including fear, anxiety, nervousness, restlessness, tremor, weakness, pallor, respiratory difficulty, dysuria, insomnia, hallucinations, convulsions, CNS depression, arrhythmias, and cardiovascular collapse with hypotension. Urinary retention may occur in patients with prostatic hypertrophy.

DRUG ABUSE AND DEPENDENCE

Rebound congestion may occur after vasoconstriction subsides when pseudoephedrine HCl is discontinued. Patients may increase the amount of drug and frequency of use, producing toxicity and perpetuating the rebound congestion. Excessive use may cause systemic effects which are more likely in the elderly. Habituation and toxic psychosis have followed long-term high-dose therapy.

OVERDOSAGE AND TREATMENT OF OVERDOSAGE

The treatment of overdosage should provide symptomatic and supportive care. Induction of emesis and gastric lavage may be performed if the patient is alert and seen within early hours after ingestion. Drug remaining in the stomach may be absorbed by the administration of activated charcoal. Stimulants should not be used because they may precipitate convulsions. If convulsions or marked CNS excitement occurs, treatment with appropriate measures is indicated. Since the effects of AlleRx™-D last up to 12 hours, the patient should be monitored for at least that length of time and treated as necessary.

DOSAGE AND ADMINISTRATION

Adults and adolescents 12 years of age and over: One tablet every 12 hours, not to exceed 2 tablets in 24 hours. AlleRx™-D is not recommended for children under 12 years of age.

HOW SUPPLIED

Bottles of 60 Tablets (NDC 10122-702-60), yellow, capsule-shaped and scored debossed with "CBP" on one side and "01" to the right of the score on the other side, each containing 120 mg of pseudoephedrine HCl and 2.5 mg of methscopolamine nitrate.

Keep out of reach of pediatric population.

Store at controlled room temperature between 20° and 25°C (68° and 77°F), see Controlled Room Temperature.

Distributed by Cornerstone Biopharma, Inc., Cary, NC 27518.

R_x Only



500353
CBA749B1107
Rev. 11/07