

DECONGEX S.R.

Capsules

Composition

Each capsule contains:

Pseudoephedrine hydrochloride	120 mg
Chlorpheniramine maleate	8 mg

In a slow-release formulation designed for oral bid dosage.

Action

Pseudoephedrine hydrochloride is a nasal decongestant, Chlorpheniramine maleate is an antihistamine. Pseudoephedrine HCl produces peripheral effects similar to those of ephedrine and central effects similar to, but less intense than amphetamines. It has the potential for excitatory side effects. At the recommended doses, it has little or no pressor effect in normotensive adults.

Chlorpheniramine possesses anticholinergic and sedative effects. It is considered one of the most effective and least toxic of the histamine antagonists. It is also an H₁ receptor antagonist. It antagonizes many of the pharmacologic actions of histamine and prevents released histamine from dilating capillaries and causing edema of the respiratory mucosa.

Indications

Deconex SR is indicated for the relief of nasal and eustachian tube congestion, which is associated with common cold, sinusitis and acute upper respiratory infections. It is also indicated for the symptomatic relief of perennial and seasonal allergic rhinitis and in vasomotor rhinitis.

Decongestants, in combination with antihistamines, have been used to relieve eustachian tube congestion that is associated with acute eustachian salpingitis, acrotitis and serious otitis media.

Contraindications

- Sympathomimetic amines are contraindicated in patients with severe hypertension, severe coronary artery disease and in patients on MAO inhibitors therapy.
- Antihistamines are contraindicated in patients who are suffering from narrow-angle glaucoma, urinary retention, peptic ulcer, during asthmatic attack, and in patients on MAO inhibitors.
- The drug is contraindicated in patients hypersensitive to any of the ingredients.

Warnings

Use in the elderly

The elderly are more likely to have adverse reactions to sympathomimetics and over dosage of sympathomimetics in this age group may cause hallucination, convulsions, CNS depression and death. Deconex must be used with caution in patients with increased intraocular pressure, cardiovascular disease, and hypertension or in patients with a history of bronchial asthma. Do not exceed recommended doses, since at higher doses, nervousness, dizziness or sleeplessness may occur.

Pregnancy

Category C

Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Adverse Reactions

Some hyper-reactive patients may display ephedrine-like reactions such as tachycardia, palpitations, headache, dizziness, or nausea. Patients sensitive to antihistamines may experience mild sedation. Sympathomimetic drugs have been associated with certain untoward reactions including fear, tenseness, weakness, restlessness, insomnia, pallor, respiratory difficulty, dysuria, hallucinations, convulsions, anxiety, tremor, CNS depression, arrhythmias and cardiovascular collapse with hypotension.

Possible side effects of antihistamines are drowsiness, dizziness, dry mouth, anorexia, headache, nervousness, nausea, blurring of vision, heartburn, and very rarely, dermatitis.

Precautions

Decongex must be used cautiously in patients with diabetes, hypertension, cardiovascular disease and hyper-reactivity to ephedrine. Antihistamines may cause drowsiness, hence ambulatory patients who operate machinery or motor vehicles should be cautioned accordingly.

Drug Interactions

MAO inhibitors and beta-adrenergic blockers increase the effect of sympathomimetics. Sympathomimetics may reduce the antihypertensive effects of methyldopa, mecamlamine, reserpine and veratrum alkaloids. Concomitant use of antihistamines with alcohol or tricyclic antidepressants, barbiturates, and with other CNS depressants may have additive effects.

Dosage and Administration

One capsule every 12 hours.

This drug is not recommended for children who are less than 12 years of age.

Over Dosage

In cases of over dosage, the patient should be induced to vomit even if emesis has occurred spontaneously; however, vomiting should not be induced in patients with impaired consciousness. Precautions against aspiration should be taken, especially in infants and children. Ipecac syrup is the preferred method to induce vomiting. The action of ipecac is facilitated by administration of eight to twelve fluid ounces of water. If emesis does not occur, ipecac dose should be repeated. Following emesis, activated charcoal may absorb any drug remaining in the stomach.

If vomiting is not successful, gastric lavage should be performed. Isotonic and one-half isotonic saline are the lavage solutions of choice.

Treatment of signs and symptoms of over dosage is symptomatic and supportive.

Presentation

Box of 8 capsules.