



**Levall G**  
Capsules

**R Only**

PIN040701 ISS. 06/07

**DESCRIPTION:**

Each Levall G Capsule is used for oral administration.

Each capsule contains:  
Guafenesin . . . . . 400 mg  
(immediate-release)  
Pseudoephedrine  
HCl . . . . . 90 mg  
(extended-release)

Guafenesin is an expectorant having the chemical name, 1,2-propanediol, 3-(2-methoxyphenoxy)-, (-).

Pseudoephedrine hydrochloride is an adrenergic (vasoconstrictor). The chemical name is benzene-methanol,  $\alpha$ -[1-(methylamino)ethyl]-, [S-(R\*, R\*)], hydrochloride.

Inactive ingredients: FD&C Red #40, FD&C Blue #1, Gelatin, Iron Oxide Black Ink, Povidone, Shellac, Starch, Sugar, Talc and Titanium Dioxide.

**CLINICAL PHARMACOLOGY:**

Pseudoephedrine hydrochloride is an orally indirect acting sympathomimetic amine and 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. The vasoconstriction action of pseudoephedrine is similar to that of ephedrine. In the usual dose it has minimal vasopressor effects. Pseudoephedrine 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 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, parhydroxylation, and oxidative deamination.

Guafenesin promotes lower respiratory tract drainage by thinning bronchial secretions, and facilitates removal of viscous, inspissated mucus. By reducing the viscosity of secretions, guafenesin increases the efficiency of the cough reflex and of the ciliary action in removing accumulated secretions from the trachea and bronchi.

**INDICATIONS AND USAGE:**

Levall G is indicated for the temporary symptomatic relief of sinusitis, bronchitis, pharyngitis, and the common cold when these

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**INDICATIONS AND USAGE:**

Levall G is indicated for the temporary symptomatic relief of sinusitis, bronchitis, pharyngitis, and the common cold when these conditions are associated with nasal congestion and viscous mucus in the lower respiratory tract.

**CONTRAINDICATIONS:**

Patients with hypersensitivity or idiosyncrasy to any of its ingredients. Sympathomimetic amines are contraindicated in patients with severe hypertension, severe coronary artery disease and patients on MAO inhibitor therapy.

**WARNINGS:**

Sympathomimetic amines should be used judiciously and sparingly in patients with hypertension, diabetes, ischemic heart disease, hyperthyroidism, increased intraocular pressure and prostatic hypertrophy. See Contraindications. Sympathomimetic amines may produce CNS stimulation and convulsions or cardiovascular collapse with accompanying hypotension. The elderly (60 years and older) are more likely to exhibit adverse reactions. Do not exceed recommended dosage.

**PRECAUTIONS:**

**General:** Should be used with caution in patients with diabetes, hypertension, cardiovascular disease and hyperreactivity to sympathomimetic amines.

**Information for Patients:**

Do not crush or chew Levall G capsules prior to swallowing.

**Drug Interactions:**

Monamine oxidase (MAO) inhibitors and beta-adrenergic blockers increase the effect of sympathomimetic amines. Sympathomimetic amines may reduce the antihypertensive effects of methyl dopa, mecaramylamine and reserpine.

**Drug /Laboratory Test**

**Interactions:** Guaifenesin has been reported to interfere with clinical laboratory determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and urinary vanillylmandelic acid (VMA).

**Pregnancy Category C:**

Animal reproduction studies have not been conducted with Levall G. It is also not known whether Levall G can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Levall G should be given to a pregnant woman only if clearly needed.

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**Nursing Mothers:** It is not known whether the drugs in Levall G are excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or discontinue the product, taking into account the importance of the drug to the mother.

**Pediatric Use:** Safety and effectiveness of Levall G in children below the age of 6 have not been established.

**ADVERSE REACTIONS:** Sympathomimetic amines may cause tachycardia, palpitations, nervousness, insomnia, restlessness, headache, gastric irritation, and irritability. Sympathomimetic amines have been associated with certain untoward reactions including fear, anxiety, tenseness, 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 prostate hypertrophy. Guafenesin may cause nausea, vomiting, diarrhea, and gastric irritation.

**OVERDOSAGE:** The treatment of overdose 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. Use of a short-acting barbiturate is recommended if convulsions or marked CNS excitement occur. Since the effects of Levall G may last up to 12 hours, the patient should be monitored for at least that length of time and treated as necessary.

**DOSAGE AND ADMINISTRATION:** Usual Dosage: Adults and children 12 years and older - 1 capsule every 12 hours not to exceed 2 capsules in 24 hours. Children 6-12 years - once daily, not to exceed 1 capsule in 24 hours. **This product not recommended for children under 6 years of age.**

**WARNING: KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CON-**

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**RECOMMENDED STORAGE:** Store at controlled room temperature 15°-30°C (59°-86°F).

**Dispense in tight, light-resistant containers as defined in USP/NF, with a child-resistant closure.**

**HOW SUPPLIED:** Levall G are clear and opaque red capsules coded "Levall | G" in bottles of 100 NDC 66813-035-01.

**Rx Only**

Manufactured for:

 **ATHLON**  
PHARMACEUTICALS, INC.

Birmingham, AL 35209

PIR040701  
ISS. 06/07



