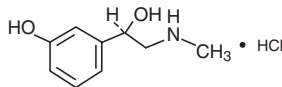
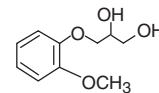


Extendryl® G (guaifenesin and phenylephrine hydrochloride)
Extended Release Tablets
Rx Only
Patent Pending



Phenylephrine hydrochloride is an orally effective nasal decongestant. Chemically it is (S)-3-hydroxy- α -[(methylamino) methyl] benzenemethanol hydrochloride.
 $C_9H_{13}NO_2 \cdot HCl$ M.W. 203.67



Guaifenesin is an expectorant. Chemically, it is 3-(2-methoxyphenoxy) - 1, 2 - propanediol.
 $C_{10}H_{14}O_4$ M.W. 198.22

Extendryl G Tablets also contain the following inactive ingredients: microcrystalline cellulose, hydroxypropyl methylcellulose, croscarmellose sodium, silicon dioxide and magnesium stearate.

CLINICAL PHARMACOLOGY:

Phenylephrine hydrochloride, a sympathomimetic amine, acts predominantly on α -adrenergic receptors in the mucosa of the respiratory tract to produce vasoconstriction that increases peripheral resistance, resulting in an increase in both systolic and diastolic blood pressure. Accompanying the pressor response is a marked reflex bradycardia due to increased vagal activity. It produces vasoconstriction that lasts longer than that produced by ephedrine and epinephrine, and in therapeutic doses, produces little or no central nervous system (CNS) stimulation. Phenylephrine has reduced bioavailability from the gastrointestinal tract because of first pass metabolism by monoamine oxidase in the stomach and liver. Guaifenesin is an expectorant which increases respiratory tract fluid secretions and helps to loosen phlegm and bronchial secretions. By reducing the viscosity of secretions, guaifenesin increases the efficiency of the cough reflex and of ciliary action in removing accumulated secretions from the trachea and bronchi. Guaifenesin is readily absorbed from the gastrointestinal tract and is rapidly metabolized and excreted in the urine. Guaifenesin has a plasma half-life of one hour. The major urinary metabolite is (2-methoxyphenoxy) lactic acid.

INDICATIONS AND USAGE:

Extendryl G Tablets are indicated for the relief of nasal congestion due to the common cold, hay fever or other upper respiratory allergies and nasal congestion associated with sinusitis; to promote nasal or sinus drainage; for the relief of Eustachian tube congestion; for adjunctive therapy in serous otitis media; for the symptomatic relief of respiratory conditions characterized by dry, nonproductive cough and in the presence of tenacious mucus and/or mucus plugs in the respiratory tract.

CONTRAINDICATIONS:

Extendryl G Tablets are contraindicated in individuals with known hypersensitivity to sympathomimetics or any of the ingredients, severe hypertension or in patients receiving MAO inhibitors.

PRECAUTIONS:

General: DO NOT CRUSH OR CHEW EXTENDRYL G TABLETS BEFORE INGESTION TO PRESERVE THE LONG-ACTING EFFECT.

Information for Patients As with other sympathomimetic drugs, Extendryl G Tablets should be used with caution in the presence of hypertension, hyperthyroidism, diabetes, heart disease, peripheral vascular disease, glaucoma and prostatic hypertrophy.

Drug Interactions: Beta adrenergic blockers and MAO inhibitors may potentiate the pressor effect of phenylephrine. Concurrent use of digitalis glycosides may increase the possibility of cardiac arrhythmias. Sympathomimetics may reduce the hypotensive effects of guanethidine, mecamylamine, methyl dopa, reserpine and veratrum alkaloids. Concurrent use of tricyclic antidepressants may antagonize the effects of phenylephrine. Use of other vasopressor drugs during halothane anesthesia may cause serious cardiac arrhythmias.

Drug/Laboratory Test Interactions: Guaifenesin interferes with the colorimetric determination of 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA). Administration of the drug should be discontinued 48 hours prior to the collection of urine specimens for such tests. Carcinogenesis, Mutagenesis, Impairment of

Fertility: There are no animal or in vitro studies on the combination product phenylephrine hydrochloride and guaifenesin to evaluate carcinogenesis, mutagenesis, and impairment of fertility.

Pregnancy: Pregnancy Category C: Animal reproduction studies have not been conducted with this product. It is also not known whether this product can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This product should be used in pregnant woman only if the potential benefit justifies risk to the fetus.

Nursing Mothers: Small amounts of phenylephrine are excreted in breast milk. Use of this product by nursing mothers is not recommended because of the higher than usual risk for infants from sympathomimetic amines. It is not known if guaifenesin is excreted in human milk.

Pediatric Use: Safety and effectiveness of this product in pediatric patients below the age of 6 years have not been established. This product contains a fixed dose of phenylephrine hydrochloride in an extended release formulation. Very young children may be more sensitive to the effects, especially the vasopressor effects, of sympathomimetic amines like phenylephrine. Demonstrate safe use of a short-acting sympathomimetic amine before use of an extended-release formulation in pediatric patients. Appropriate studies on the relationship of age to the effects of guaifenesin have not been performed in the pediatric population.

Geriatric Use: Patients aged 60 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 death. Demonstrate safe use of a short-acting sympathomimetic amine before use of an extended action formulation in geriatric patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or drug therapy.

ADVERSE REACTIONS:

Hyperreactive individuals may display ephedrine-like reactions 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. Guaifenesin is well tolerated and has a wide margin of safety. Side effects are generally mild and infrequent. Nausea and vomiting are the most frequently occurring side effects.

DRUG ABUSE AND DEPENDENCE:

Central nervous system stimulants have been abused. At high doses, subjects commonly experience an elevation of mood, a sense of increased energy and alertness, and decreased appetite. Some individuals become anxious, irritable, and loquacious. In addition to the marked euphoria, the user experiences a sense of markedly enhanced physical strength and mental capacity. With continued use, tolerance develops, the user increases the dose, and toxic signs and symptoms appear. Depression may follow rapid withdrawal.

OVERDOSAGE:

Since the effects of Extendryl G Tablets may last up to 12 hours, treatment of overdosage directed towards patients supporting the patient and reversing the effects of the drug should be continued for at least that length of time. Saline cathartics may be useful in hastening the evacuation of unreleased medication.

Signs and symptoms: Overdosage with sympathomimetic amines can cause cardiac arrhythmias, cerebral hemorrhage and pulmonary edema. It can also cause palpitation, tremor, dizziness, vomiting, fear, labored breathing, headache, dryness of mouth, pallor, weakness, panic, anxiety, confusion, hallucinations, and delirium. Overdosage with guaifenesin is unlikely to produce toxic effects since its toxicity is low. Guaifenesin, when administered by stomach tube to test animals in doses up to 5 gm/kg, produced no signs of toxicity.

Treatment: Treatment of acute overdosage should be based upon treating the patient for the symptoms of overdosage of phenylephrine as follows: The treatment of overdosage should provide symptomatic and supportive care. If the amount ingested is considered dangerous or excessive, induce vomiting with ipecac syrup unless the patient is convulsing, comatose, or has lost the gag reflex, in which case perform gastric lavage using a large bore tube. If indicated, follow with activated charcoal and a saline cathartic.

DOSAGE AND ADMINISTRATION:

Adults and children 12 years of age and older: 1 tablet every 12 hours.

Children 6 to under 12 years of age: 1/2 tablet every 12 hours, not to exceed 1 tablet in 24 hours.

Not recommended for children under 6 years of age.

Tablets may be broken in half without affecting the release of the medication but not crushed or chewed.

HOW SUPPLIED:

Extendryl G Tablets are supplied as a white caplet debossed "AP 204" in bottles of 100, NDC 14629-204-01. Dispense in a tight, light resistant container as defined in USP/NF with a child-resistant closure.

STORAGE:

Store at 20 to 25°C (68 to 77°F) [See USP Controlled Room Temperature].

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

Rx Only

Manufactured for:
Auriga Pharmaceuticals, LLC
An Auriga Laboratories Company
Norcross, GA 30092
Patent Pending