

POLARAMINE* EXPECTORANT

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Brand of dexchlorpheniramine maleate, pseudoephedrine sulfate and guaifenesin.
Antihistaminic/Decongestant Expectorant

DESCRIPTION: Each teaspoonful (5 ml) of POLARAMINE Expectorant contains 2 mg dexchlorpheniramine maleate, 20 mg pseudoephedrine sulfate and 100 mg guaifenesin. Inactive ingredients: Sodium benzoate, menthol, ethanol, chocolate cream flavor, cherry imitation flavor, lemon extract terpeneless flavor, sorbitol, propylene glycol, sucrose and purified water.

ACTIONS: POLARAMINE Expectorant combines the antihistaminic action of dexchlorpheniramine maleate with the vasoconstrictive properties of pseudoephedrine sulfate; guaifenesin increases respiratory tract fluid output and eases expectoration.

INDICATIONS AND USAGE: POLARAMINE Expectorant is indicated for the relief of cough and complications associated with allergic disorders and for relief of the allergic manifestations of respiratory disorders, such as seasonal rhinitis and vasomotor rhinitis.

DOSAGE AND ADMINISTRATION: Adults and children 12 years or older: one or two teaspoonfuls 3 or 4 times a day. Children 6 to 12 years: one-half to one teaspoonful 3 or 4 times a day. Children 2 to 6 years: one-quarter to one-half teaspoonful 3 or 4 times a day.

DRUG INTERACTIONS: Monamine oxidase (MAO) inhibitors prolong and intensify the effects of antihistamines; severe hypotension may occur. Concomitant use of antihistamines with alcohol, tricyclic antidepressants, barbiturates, or other central nervous system depressants may potentiate the sedative effect of dexchlorpheniramine. The action of oral anticoagulants may be decreased by antihistamines.

Coadministration of pseudoephedrine containing drugs and MAO inhibitors has been associated with hypertensive reactions, including hypertensive crisis. Therefore, POLARAMINE should not be given to patients treated with a MAO inhibitor or within two weeks of discontinuing such treatment in patients with severe hypertension, since a severe hypertensive crisis may be precipitated.

Pseudoephedrine should not be used with ganglionic blocking agents or with adrenergic blocking agents. Increased ectopic pacemaker activity can occur when pseudoephedrine is used concomitantly with digitalis. Antacids increase the rate of absorption of pseudoephedrine; kaolin decreases it.

Drug/Laboratory Test Interactions - the in vitro addition of pseudoephedrine to sera containing the cardiac isoenzyme MB of serum creatinine phosphokinase progressively inhibits the activity of the enzyme.

Guaifenesin has been shown to produce a color interference with certain clinical laboratory determinations of 5-hydroxy-indole-acetic acid (5-HIAA) and vanilylmandelic acid (VMA).

ADVERSE REACTIONS: The physician should be alerted to the possibility of any adverse effects associated with antihistaminic and sympathomimetic drugs. Slight to moderate drowsiness is the most frequent side effect of dexchlorpheniramine maleate. Other possible side effects of antihistamines include cardiovascular, hematologic, neurologic, gastrointestinal, genitourinary and respiratory reactions. General side effects such as urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose and throat have been reported.

Sympathomimetic side effects include CNS depression, restlessness, anxiety, fear, tension, insomnia, tremor, convulsions, weakness, vertigo, dizziness, headache, flushing, pallor, respiratory difficulty, sweating, nausea, vomiting, anorexia, muscle cramps, polyuria, dysuria, vesical sphincter spasm, urinary retention. Cardiovascular effects associated with sympathomimetics include hypertension, palpitations, tachycardia, arrhythmias, anginal pain, pre-cordial distress, cardiovascular collapse.

No serious adverse reactions have been reported with guaifenesin. Nausea, gastrointestinal disturbances and drowsiness have been reported infrequently.

CONTRAINDICATIONS: POLARAMINE Expectorant is contraindicated in newborn and premature infants; in patients receiving MAO inhibitor therapy or within two weeks of discontinuing such treatment; in patients with severe hypertension, severe coronary artery disease, or hyperthyroidism; in those who have shown hypersensitivity or idiosyncrasy to its components; to adrenergic agents or to other drugs of similar chemical structure.

PRECAUTIONS: POLARAMINE Expectorant should be used with caution in patients with narrow angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, prostatic hypertrophy or bladder neck obstruction, cardiovascular disease, in those with increased intraocular pressure, hyperthyroidism, diabetes mellitus, or angina.

Patients should be warned about engaging in activities requiring mental alertness, such as driving a car or operating appliances or machinery.

Antihistamines may cause dizziness, sedation, and hypotension in patients over 60 years of age. These patients are also more likely to have adverse reactions to sympathomimetics.

Safety and effectiveness of POLARAMINE Expectorant in children under 2 years of age have not been established. May cause excitability, especially in children.

USAGE IN PREGNANCY: Safety during pregnancy has not been established. POLARAMINE Expectorant should be used during the first two trimesters of pregnancy only if clearly needed. Dexchlorpheniramine maleate should not be used in the third trimester of pregnancy because newborn and premature infants may have severe reactions to antihistamines.

NURSING MOTHERS: It is not known whether this product is excreted in human milk and therefore, caution should be exercised when administered to nursing mothers.

OVERDOSAGE INFORMATION: In the event of overdose, emergency treatment should be started immediately. In humans, the estimated lethal dose of dexchlorpheniramine is 2.5 to 5.0 mg/kg.

Manifestations: Antihistamine overdose effects may vary from central nervous system depression (sedation, apnea, diminished mental alertness, cardiovascular collapse) to stimulation (insomnia, hallucinations, tremors, or convulsions) to death. Other signs and symptoms may be dizziness, tinnitus, ataxia, blurred vision, and hypotension. Stimulation is particularly likely in children, as are atropine-like signs and symptoms (dry mouth; fixed, dilated pupils; flushing; hyperthermia; and gastrointestinal symptoms). In large doses, sympathomimetics may give rise to giddiness, headache, nausea, vomiting, sweating, thirst, tachycardia, precordial pain, palpitations, difficulty in micturition, muscular weakness and tenseness, anxiety, restlessness, and insomnia. Many patients can present a toxic psychosis with delusions and hallucinations. Some may develop cardiac arrhythmias, circulatory collapse, convulsions, coma, and respiratory failure.

Treatment: The patient should be induced to vomit even if emesis has occurred spontaneously. Pharmacologically-induced vomiting by the administration of ipecac syrup is a preferred method. However, vomiting should not be induced in patients with impaired consciousness. The action of ipecac is facilitated by physical activity and by the administration of 240 to 360 milliliters of water. If emesis does not occur within 15 minutes, the dose of ipecac should be repeated. Precautions against aspiration must be taken, especially in infants and children. Following emesis, any drug remaining in the stomach may be adsorbed by activated charcoal administered as a slurry with water. If vomiting is unsuccessful or contraindicated, gastric lavage should be performed. Isotonic and one-half isotonic saline are the lavage solutions of choice.

Saline cathartics draw water into the bowel by osmosis and therefore may be valuable for their action in rapid dilution of bowel content. Dialysis is of little value in antihistamine poisoning. After emergency treatment, the patient should continue to be medically monitored.

Treatment of the signs and symptoms of overdose is symptomatic and supportive. Stimulants (analeptic agents) should not be used.

Vasopressors may be used to treat hypotension. Short-acting barbiturates, diazepam, or paraldehyde may be administered to control seizures. Hyperpyrexia, especially in children, may require treatment with tepid water sponge baths or a hypothermic blanket. Apnea is treated with ventilatory support.

HOW SUPPLIED: Syrup, 100ml and 120ml bottles.

STORAGE: Store between 2° and 30°C.

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