POLARAMINE* Products

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Brand of dexchlorpheniramine maleate.
Antihistamine REPETABS* Tablets and Syrup.

DESCRIPTION: POLARAMINE REPETABS (Repeat Action) Tablets contain a total of 6 mg dexchlorpheniramine maleate. Inactive ingredients: acacia, calcium sulfate, sucrose, butylparaben, corn starch, rosin, oleic acid, zein, eiderdown soap, talc, tribasic calcium phosphate, stearic acid, purified siliceous earth, kaolin, carnuba wax and white wax.

Each teaspoonful (5 ml) of POLARAMINE Syrup contains 2 mg dexchlorpheniramine maleate. Inactive ingredients: sodium citrate dihydrate, sodium chloride, sucrose, sorbitol, methylparaben, propylparaben, apricot flavor, blood orange imitation flavor, menthol, ethanol, propylene glycol and purified water.

ACTIONS: POLARAMINE Products contain the antihistamine, dexchlorpheniramine maleate. Antihistamines appear to compete with histamine for cell receptor sites on effector cells.

INDICATIONS AND USAGE: POLARAMINE REPETABS Tablets, Syrup, are indicated for the symptomatic relief of seasonal and perennial rhinitis, vasomotor rhinitis, allergic conjunctivitis, urticaria, angioedema, allergic eczema, atopic dermatitis, contact dermatitis, amelioration of allergic reactions to blood or plasma, drug reactions, insect bites and dermographism. POLARAMINE can be used for the prevention and treatment of allergic reactions to injections of allergenic substances. POLARAMINE is also indicated as therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled.

DOSAGE AND ADMINISTRATION: DOSAGE SHOULD BE INDIVIDUALIZED ACCORDING TO THE NEEDS AND RESPONSE OF THE PATIENT.

POLARAMINE REPETABS Tablets 6 mg: Adults and children 12 years or older - usual dose is one in the morning and one before retiring. For the treatment of certain resistant cases, it may be desirable to administer one every eight hours.

POLARAMINE Syrup - Adults and children 12 years or older: one teaspoonful 3 or 4 times a day. Children 6 to 12 years: one-half teaspoonful 3 or 4 times a day. Children 2 to 6 years: one-quarter teaspoonful 3 or 4 times a day.

DRUG/LABORATORY TEST INTERACTIONS: Monoamine 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.

Antihistamines should be discontinued approximately 48 hours prior to skin testing procedures since these drugs may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

ADVERSE REACTIONS: The physician should be alerted to the possibility of any adverse effects associated with antihistaminic 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.

CONTRAINDICATIONS: POLARAMINE Products are contraindicated in newborn and premature infants, in patients receiving MAO inhibitor therapy and in those who have shown hypersensitivity or idiosyncrasy to any of their components or to other drugs of similar chemical structures.

PRECAUTIONS: POLARAMINE Products should be used with caution in patients with narrow angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, prostatic hypertrophy or bladder neck obstruction, cardiovascular disease including hypertension, and in those with increased intraocular pressure or hyperthyroidism. Patients should be warned about engaging in activities requiring mental alertness, such as driving a car or operating appliances, machinery.

Antihistamines may cause dizziness, sedation, and hypotension in patients over 60 years of age.

Safety and effectiveness of POLARAMINE Products have not been established in the following age groups: POLARAMINE REPETABS Tablets, 6 mg, in children under 12 years of age; POLARAMINE Syrup, in children under 2 years of age. May cause excitability, especially in children.

USAGE IN PREGNANCY: Safety during pregnancy has not been established. POLARAMINE 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 POLARAMINE Products are excreted in human milk and therefore, caution should be exercised when administered to nursing mothers.

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

Manifestations: Antihistamine overdosage 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).

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 overdosage 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: -Repetabs 6mg per Repetab in blister packs, boxes of 20.
-Syrup 2mg/5ml, 100ml and 120ml bottles.

STORAGE: Store between 2° and 30°C.

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