

REFORMULATED

Rynatan® Pediatric Suspension

IN-0714-07 Rev. 1/09

Description

Rynatan® Pediatric Suspension is an antihistamine/nasal decongestant combination available for oral administration as a *Suspension*. Each 5 mL (one teaspoonful) of the slate-purple-colored, natural strawberry- artificial currant flavored Suspension contains:

Phenylephrine Tannate	5 mg
Chlorpheniramine Tannate	4.5 mg

Other ingredients: benzoic acid, FD&C Blue No.1, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5 (see Precautions), flavors (natural and artificial), glycerin, kaolin, magnesium aluminum silicate, methylparaben, pectin, purified water, saccharin sodium, sucrose.

Clinical Pharmacology

Rynatan® Pediatric Suspension combines the sympathomimetic decongestant effect of phenylephrine with the antihistaminic action of chlorpheniramine.

Indications and Usage

Rynatan® Pediatric Suspension is indicated for symptomatic relief of the coryza and nasal congestion associated with the common cold, sinusitis, allergic rhinitis and other upper respiratory tract conditions. Appropriate therapy should be provided for the primary disease.

Contraindications

Rynatan® Pediatric Suspension is contraindicated for newborns, nursing mothers and patients sensitive to any of the ingredients or related compounds.

Warnings

Use with caution in patients with hypertension, cardiovascular disease, hyperthyroidism, diabetes, narrow angle glaucoma or prostatic hypertrophy. Use with caution or avoid use in patients taking monoamine oxidase (MAO) inhibitors, or within 14 days of stopping such treatment. This product contains an antihistamine which may cause drowsiness and may have additive central nervous system (CNS) effects with alcohol or other CNS depressants (e.g., hypnotics, sedatives, tranquilizers).

Precautions

This product contains FD&C Yellow No. 5 (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

General: Antihistamines are more likely to cause dizziness, sedation and hypotension in elderly patients. Antihistamines may cause excitation, particularly in children, but their combination with sympathomimetics may cause either mild stimulation or mild sedation.

Information for patients: Caution patients against drinking alcoholic beverages or engaging in potentially hazardous activities requiring alertness, such as driving a car or operating machinery while using this product. Patients should be warned not to use this product if they are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If patients are uncertain whether a prescription drug contains an MAOI, they should be instructed to consult a health professional before taking such a product.

Drug interactions: MAO inhibitors may prolong and intensify the anticholinergic effects of antihistamines and the overall effects of sympathomimetic agents.

Carcinogenesis, mutagenesis, impairment of fertility: No long term animal studies have been performed with Rynatan® Pediatric Suspension.

Pregnancy: Teratogenic effects: Pregnancy Category C. Animal reproduction studies have not been conducted with Rynatan® Pediatric Suspension. It is also not known whether Rynatan® Pediatric Suspension can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Rynatan® Pediatric Suspension should be given to a pregnant woman only if clearly needed.

Nursing mothers: Rynatan® Pediatric Suspension should not be administered to a nursing woman.

Adverse Reactions

To report SUSPECTED ADVERSE REACTIONS, contact Meda Pharmaceuticals Inc. at 1-800-526-3840 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Adverse effects associated with Rynatan® Pediatric Suspension at recommended doses have been minimal. The most common have been drowsiness, sedation, dryness of mucous membranes, and gastrointestinal effects. Serious side effects with oral antihistamines or sympathomimetics have been rare.

Overdosage

Signs & symptoms: May vary from CNS depression to stimulation (restlessness to convulsions). Antihistamine overdosage in young children may lead to convulsions and death. Atropine-like signs and symptoms may be prominent.

Treatment: Induce vomiting if it has not occurred spontaneously. Precautions must be taken against aspiration especially in infants, children and comatose patients. If gastric lavage is indicated, isotonic or half-isotonic saline solution is preferred. Stimulants should not be used. If hypotension is a problem, vasopressor agents may be considered.

Dosage and Administration

Administer the recommended dose every 12 hours.

Rynatan® Pediatric Suspension: *Children over six years of age* — 5 to 10 mL (1 to 2 teaspoonfuls); *Children two to six years of age* — 2.5 to 5 mL (1/2 to 1 teaspoonful); *Children under two years of age* — Titrate dose individually.

How Supplied

Rynatan® Pediatric Suspension (phenylephrine tannate 5 mg, and chlorpheniramine tannate 4.5 mg per 5 mL) in pint bottles (NDC 0037-0714-16).

Storage: Store at controlled room temperature 20°-25°C (68°-77°F).

Dispense in a tight container.

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U.S. Patents 6,037,358; 5,663,415; 5,599,846

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Printed in U.S.A.

Rev. 1/09