

Rynatuss

Tablets

IN-0717-16

Rev. 1/09

Description

RYNATUSS® Tablets are an antitussive/antihistamine/nasal decongestant/bronchodilator combination.

Each tablet contains:

Carbetapentane Tannate	60 mg
Chlorpheniramine Tannate	5 mg
Ephedrine Tannate	10 mg
Phenylephrine Tannate	10 mg

Other ingredients: corn starch, dibasic calcium phosphate, FD&C Blue No. 1, FD&C Red No. 40, magnesium stearate, methylcellulose, polygalacturonic acid, povidone, talc.

Clinical Pharmacology

RYNATUSS® Tablets combine the antitussive action of carbetapentane, the sympathomimetic decongestant effect of phenylephrine, the antihistaminic action of chlorpheniramine, and the bronchodilator action of ephedrine.

Indications and Usage

RYNATUSS® Tablets are indicated for the symptomatic relief of cough associated with respiratory tract conditions such as the common cold, bronchial asthma, acute and chronic bronchitis. Appropriate therapy should be provided for the primary disease.

Contraindications

RYNATUSS® Tablets are contraindicated for newborns, nursing mothers, and patients who are 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. Do not use in patients taking monoamine oxidase (MAO) inhibitors, or for 14 days after stopping treatment with an MAOI.

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

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 RYNATUSS® Tablets.

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

Nursing mothers: RYNATUSS® Tablets 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 RYNATUSS® Tablets 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 and 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.

RYNATUSS® Tablets: Adults — 1 to 2 tablets.

How Supplied

RYNATUSS® Tablets are mauve, capsule-shaped, scored on one side and imprinted RYNATUSS 717 on the other side, containing in each tablet: carbetapentane tannate 60 mg, chlorpheniramine tannate 5 mg, ephedrine tannate 10 mg, phenylephrine tannate 10 mg, available in bottles of 100 (NDC 0037-0717-92).

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

Dispense in a tight container.

Protect from moisture.

Produced under license from
JFC Technologies
Bound Brook, NJ, U.S.A.

U.S. Patents 5,599,846; 5,663,415

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