

**Ryna<sup>®</sup>-12**  
Tablets  
**Ryna-12 S<sup>®</sup>**  
Suspension  
IN-0673-03 Rev. 3/09

#### Description

RYNA<sup>®</sup>-12 is an antihistamine/nasal decongestant combination available for oral administration as *Tablets* and as *Suspension*. Each tablet contains:

Phenylephrine Tannate	25 mg
Pyrilamine Tannate	60 mg

Other ingredients: corn starch, dibasic calcium phosphate, magnesium stearate, methylcellulose, polygalacturonic acid, talc.

Each 5 mL (one teaspoonful) of the pink-colored, natural strawberry-artificial currant flavored Suspension contains:

Phenylephrine Tannate	5 mg
Pyrilamine Tannate	30 mg

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

#### Clinical Pharmacology

RYNA<sup>®</sup>-12 combines the sympathomimetic decongestant effect of phenylephrine with the antihistaminic action of pyrilamine.

#### Indications and Usage

RYNA<sup>®</sup>-12 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

RYNA<sup>®</sup>-12 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. These products contain 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 these products. Patients should be warned not to use these products 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 RYNA<sup>®</sup>-12.

*Pregnancy:* Teratogenic effects: Pregnancy Category C. Animal reproduction studies have not been conducted with RYNA<sup>®</sup>-12. It is also not known whether RYNA<sup>®</sup>-12 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. RYNA<sup>®</sup>-12 should be given to a pregnant woman only if clearly needed.

*Nursing mothers:* RYNA<sup>®</sup>-12 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](http://www.fda.gov/medwatch).**

Adverse effects associated with RYNA<sup>®</sup>-12 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 overdose 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.

RYNA<sup>®</sup>-12 Tablets: Adults — 1 or 2 tablets.

Children 6 to 11 years — 1/2 or 1 tablet. RYNA-12 S<sup>®</sup> 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

RYNA<sup>®</sup>-12 Tablets (phenylephrine tannate 25 mg, and pyrilamine tannate 60 mg): buff-colored, capsule-shaped, scored on one side and imprinted WALLACE 673 on the other side. The tablets are available in bottles of 100 (NDC 0037-0673-10).

RYNA-12 S<sup>®</sup> Suspension (phenylephrine tannate 5 mg, and pyrilamine tannate 30 mg per 5 mL) in 4 fl oz unit of use container with a 10 mL graduated oral syringe and fitment (NDC 0037-0655-04, labeled RYNA-12 S<sup>®</sup>).

*Storage:* RYNA<sup>®</sup>-12 Tablets — Store at controlled room temperature 20°-25°C (68°-77°F).

RYNA-12 S<sup>®</sup> Suspension — Store at controlled room temperature 20°-25°C (68°-77°F).

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