RYNEX PSE- brompheniramine maleate and pseudoephedrine hydrochloride liquid
EDWARDS PHARMACEUTICALS, INC.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

RYNEX PSE

Drug Facts

Active Ingredients (in each 5 mL teaspoonful)	***Purpose***
Brompheniramine Maleate 1 mg	Antihistamine
Pseudoephedrine HCl 15 mg	Decongestant

Uses

temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other respiratory allergies:

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- nasal congestion 'reduces swelling of nasal passages

Warnings

On not exceed recommended dosage.

Do not use this product

- if you are now taking a prescription monoamine oxidase inhibitor (MA0I) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MA0I drug. If you do not know if your prescription drug contains an MA0I, ask a doctor or pharmacist before taking this product

Do not use this product, unless directed by a doctor, if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- heart disease
- thyroid disease
- diabetes mellitus
- difficulty in urination due to enlargement of the prostate gland

Do not lake this product if you are taking sedatives or tranquilizers, without first consulting your doctor.

When using this product

- excitability may occur, especially in children
- may cause drowsiness
- alcohol, sedatives and tranquilizers may increase drowsiness effect
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery

Stop use and ask doctor If

- nervousness, dizziness, or sleeplessness occur
- If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor
- new symptoms occur

Keep out **of reach of children.**

In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.

Directions

Do not exceed recommended dosage

Adults and children 12 years of age and over:	**4** teaspoonfuls (20 mL) every 4 to 6 hours, not to exceed 16 teaspoonfuls in 24 hours
Children 6 to under 12 years of age:	2 teaspoonfuls (10 mL) every 4 to 6 hours, not to exceed 8 teaspoonfuls in 24 hours
Children under 6 years of age	Consult a doctor

Other information

Store at 59° - 86° F (15° - 30 C) [see USP for Controlled Room Temperature]

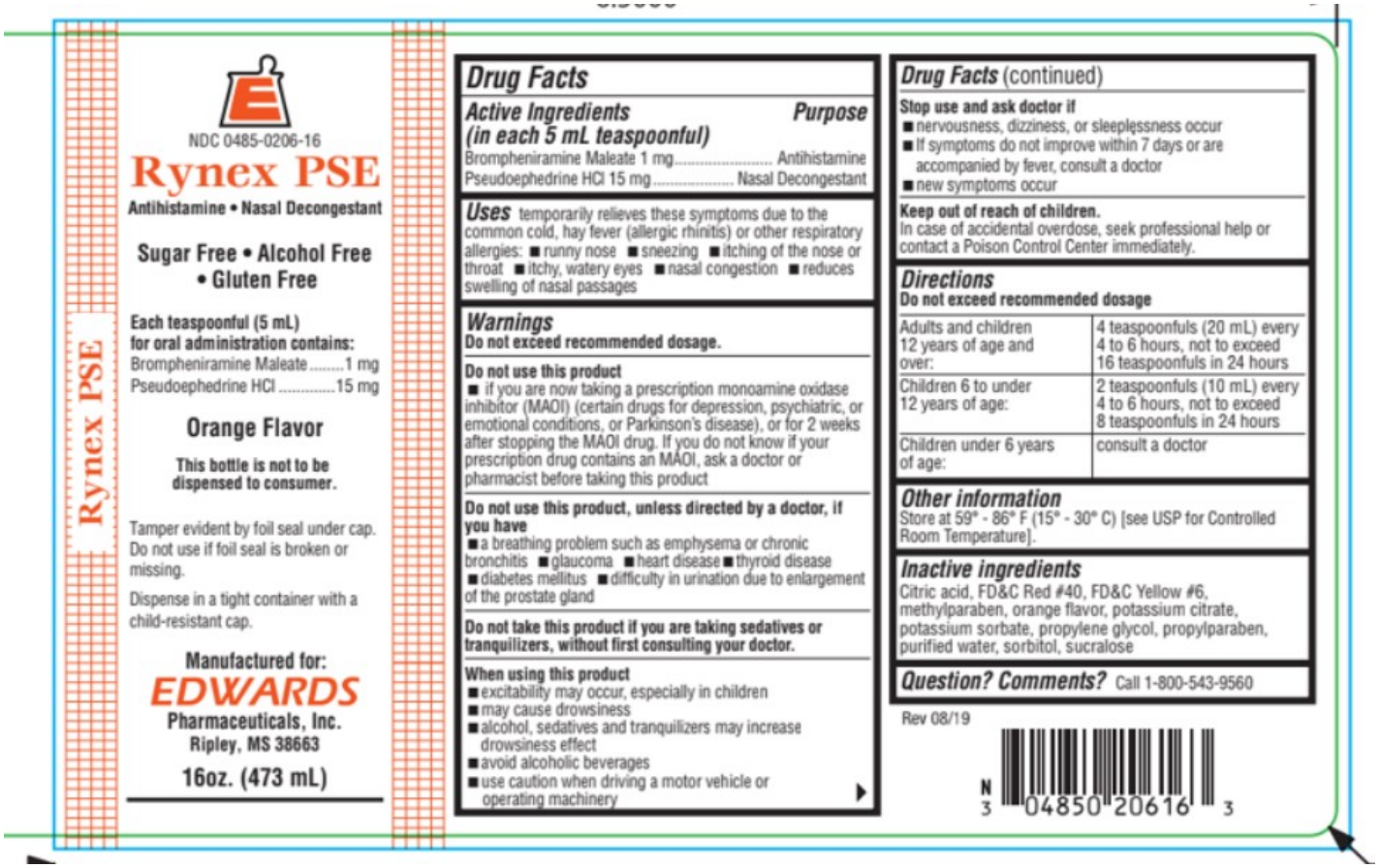
Inactive ingredients

Citric Acid, FD&C Red #40, FD&C Yellow #6, Methyl Paraben, Orange flavor, Potassium Citrate, Potassium Sorbate, Propyl Paraben, Propylene Glycol, Purified Water, Sorbitol Solution 70%, Sucralose

Question? Comments?

Call 1-800-543-9560

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label



NDC 00485-0206-16

Rynex PSE

Antihistamine • Decongestant

Sugar Free • Alcohol Free •

Gluten Free

Each teaspoonful (5 mL)

for oral administration contains:

Brompheniramine Maleate 1 mg

Pseudoephedrine HCl 15 mg

Orange Flavor

FOR PROFESSIONAL USE ONLY

This bottle is not to be

dispensed to consumer.

Tamper evident by foil seal under cap.

Do not used foil seal is broken or missing.

Dispense in a tight container with a child-

resistant cap.

Manufactured for:

EDWARDS

Pharmaceuticals, Inc.

Ripley, MS 38663

16oz. (473 mL)

RYNEX PSE

brompheniramine maleate and pseudoephedrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0485-0206
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	1 mg in 5 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	15 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	orange	**Score**	

Shape		**Size**	
Flavor	ORANGE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0485-0206-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/07/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/07/2011	

Labeler - EDWARDS PHARMACEUTICALS, INC. (195118880)

Revised: 1/2024 EDWARDS PHARMACEUTICALS, INC.