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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

RYNEX PE

Drug Facts

Active Ingredients (in each 5 nil teaspoonful)	***Purpose***
Brompheniramine Maleate 1 mg	Antihistamine
Phenylephrine HCl 2.5 mg	Nasal 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 passage

Warnings

Do not exceed recommended dosage.

Do not take 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 MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

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

Ask a doctor before use if you are taking sedatives or tranquilizers.

When using this product

- excitability may occur, especially in children
- may cause drowsiness
- sedalives 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

If pregnant or breast feeding, ask a health professional before use.

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 hours, not to exceed 24 teaspoonfuls in 24 hours, or as directed by a doctor.
Children 6 to under 12 years of age:	2 teaspoonfuls(10 mL) every 4 hours, not to exceed 1 teaspoonfuls in 24 hours, or as directed by a doctor.
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

Bubblegum Flavor, Citric Acid, FD&C Red #40, Methyl Paraben, Potassium Citrate, Potassium Sorbate, Propyl Paraben, Propylene Glycol, Purified Water, Sorbitol Solution 70%, Sucralose.

Questions Comments?

Call 1-800-543-9560

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

Rynex PE

E

NDC 0485-0202-16

Rynex PE

Antihistamine • Nasal Decongestant

Sugar Free • Alcohol Free

• Gluten Free

Each teaspoonful (5 mL)

for oral administration contains:

Brompheniramine Maleate 1 mg

Phenylephrine HCl 2.5 mg

Bubblegum Flavor

FOR PROFESSIONAL USE ONLY

Tamper evident by foil seal under cap.

Do not use if foil seal is broken or

missing.

Manufactured for:

EDWARDS

Pharmaceuticals, Inc.

Ripley, MS 38663

16oz. (473 mL)

RYNEX PE

brompheniramine maleate and pseudoephedrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0485-0202
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)	
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	pink	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0485-0202-16	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
OTC monograph final	part341	03/07/2011	

Labeler - EDWARDS PHARMACEUTICALS, INC. (195118880)

Establishment

Name	Address	ID/FEI	Business Operations
TG United		830980947	manufacture(0485-0202)

Revised: 5/2020 EDWARDS PHARMACEUTICALS, INC.