**RYNEX PSE- 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.*

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**RYNEX PSE**

*Drug Facts*

| ***Active Ingredients (in each 5 mL teaspoonful)*** | ***Purpose*** |
|---|---|
| Brompheniramine Maleate 1 mg | Antihistamine |
| Pseudoephedrine HCI 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]

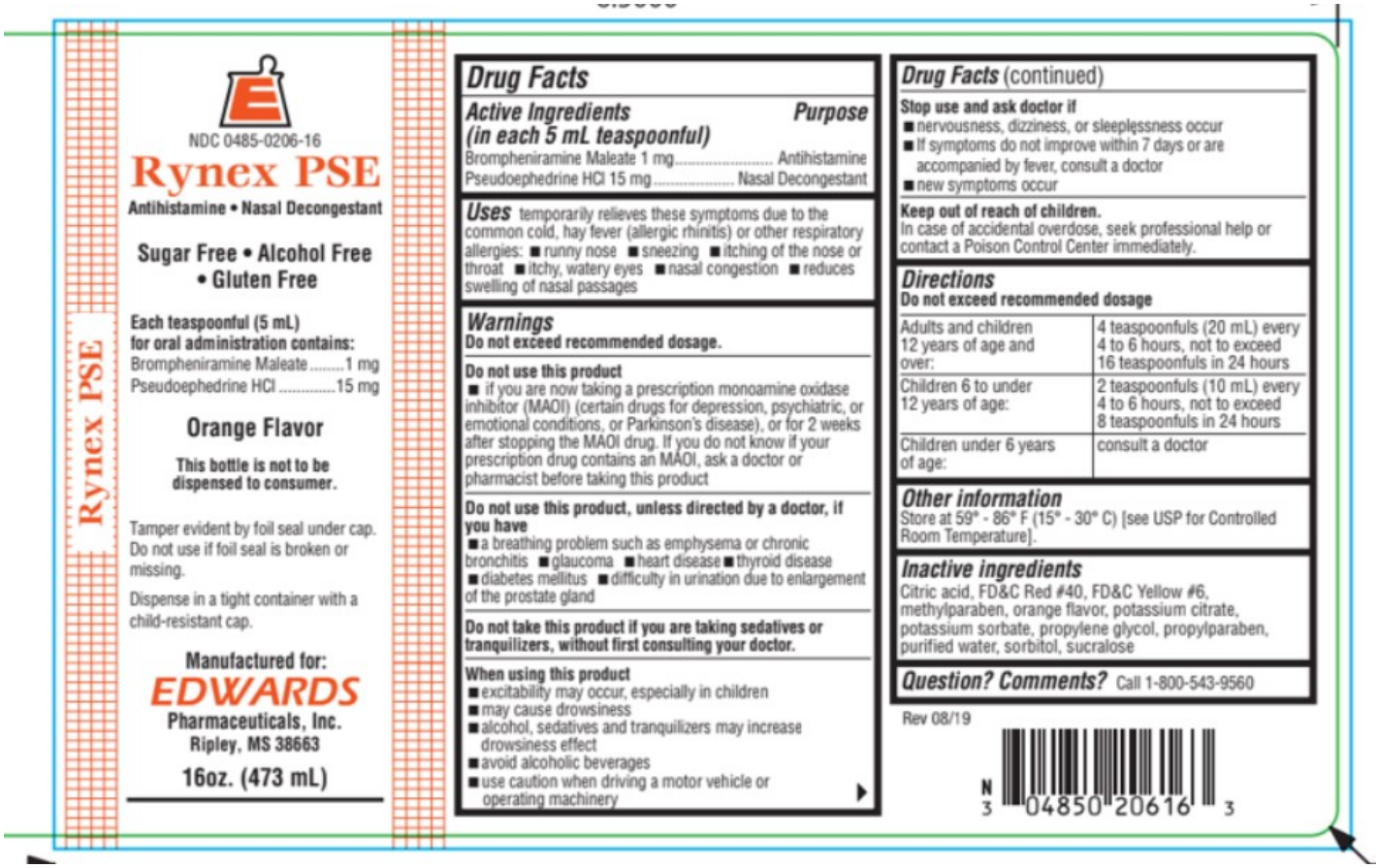
**Inactive ingredients**

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 HCI 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 |
|---|---|---|---|
| OTC monograph final | part341 | 03/07/2011 | |

## Labeler - EDWARDS PHARMACEUTICALS, INC. (195118880)

Revised: 5/2020 EDWARDS PHARMACEUTICALS, INC.