

## Racepinephrine Inhalation Solution, USP 2.25%

### *Drug Facts*

#### **Active ingredient (in each 0.5 ml)**

Racepinephrine, USP 11.25 mg (as 13.5 mg of Racepinephrine HCl, USP).

#### **Purpose**

Bronchodilator

#### **Uses**

For temporary relief of mild symptoms of intermittent asthma:

- Wheezing
- Tightness of chest
- Shortness of breath

#### **Warnings**

##### **Asthma alert**

**Because asthma may be life threatening, see a doctor if you:**

- Are not better in 20 minutes
- Get worse
- Need more than 12 inhalations in 24 hours
- Use more than 9 inhalations in 24 hours for 3 or more days a week
- Have more than 2 asthma attacks in a week

These may be signs that your asthma is getting worse.

##### **Do not use:**

- Unless a doctor said you have asthma
- If you 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 you do not know if your prescription drug contains a MAOI, ask a doctor or pharmacist before taking this product.
- If product is brown in color or cloudy

##### **Ask a doctor before use if you have:**

- Ever been hospitalized for asthma
- Heart disease
- High blood pressure
- Diabetes
- Thyroid disease
- Seizures
- Narrow angle glaucoma
- A psychiatric or emotional condition
- Trouble urinating due to an enlarged prostate gland

##### **Ask a doctor or pharmacist before use if you are:**

- Taking prescription drugs for asthma, obesity, weight control, depression, or psychiatric or emotional conditions.
- Taking any drug that contains phenylephrine, pseudoephedrine, ephedrine, or caffeine (such as for allergy, cough-cold, or pain).

##### **Stop use and ask a doctor if:**

- Your asthma is getting worse (See [Asthma alert](#))
- You have difficulty sleeping
- You have a rapid heartbeat
- You have tremors, nervousness, or seizure

##### **When using this product:**

**Your blood pressure or heart rate may go up. This could increase your risk of heart attack or stroke, which may cause death.**

- **Your risk of heart attack or stroke increases if you:**
  - **Have a history of high blood pressure or heart disease**
  - **Take this product more frequently or take more than the recommended dose.**

- Avoid foods or beverages that contain caffeine
- Avoid dietary supplements containing ingredients reported or claimed to have a stimulant effect.
- **If pregnant or breast-feeding**, ask a health professional before use.
- **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

- The ingredient is used in an aqueous solution at a concentration equivalent to 1 percent epinephrine.
- **Do not use more than directed**
- **For use in a hand-held rubber bulb nebulizer:**
  - Add 0.5 ml (contents of one vial) of solution to nebulizer.
- Adults and children 4 years of age and over:
  - 1 to 3 inhalations not more often than every 3 hours.
  - Do not use more than 12 inhalations in 24 hours.
  - The use of this product by children should be supervised by an adult.
- Children under 4 years of age: ask a doctor.

#### **Other Information**

- Protect from light. Avoid excessive heat. Protect from freezing.
- Store between 2°C and 25°C (36°F and 77°F).
- How Supplied: S<sub>2</sub><sup>®</sup> Racepinephrine Inhalation Solution, USP 2.25% is supplied in 0.5 ml sterile unit-of-use vials.

NDC 0487-5901-99 30 vials, each vial in an individual foil pouch.

#### **Inactive Ingredients**

Ascorbic acid, citric acid, edetate disodium, water for injection.

#### **Questions?**

**1-800-443-4313**

Monday through Friday, 8:00 a.m. to 5:00 p.m. (Eastern Standard Time).

Manufactured By:

Nephron Pharmaceuticals Corporation

West Columbia, SC 29172

#### **PACKAGE LABEL, PRINCIPAL DISPLAY PANEL**

**Principle Display - Pouch Label (Individually Wrapped Vial)**

**NDC 0487-5901-99**

NDC 0487-5901-99



**FOR ORAL INHALATION ONLY**

**Drug Facts**

**Active ingredient:**.....**Purpose**  
Racpinephrine, USP,.....**Bronchodilator**  
Each 0.5 ml contains 11.25 mg  
(as 13.5 mg of Racpinephrine HCl, USP).

**Uses:** For temporary relief of shortness of breath, tightness of chest, and wheezing due to bronchial asthma.

**See product carton for detailed information on Uses, Warnings, and Directions.**

**Other Information:**  
Store between 2° and 25°C (36° and 77°F). Protect from light. Protect from freezing.

**Inactive Ingredients:** Ascorbic acid, citric acid, edetate disodium, water for injection.

**TAMPER EVIDENT FEATURE:**  
Do not use this product if the pouch is damaged or torn.

**Do not use this product if it is brown in color or cloudy.**

**STERILE**

One 0.5 ml Unit-of-Use Vial



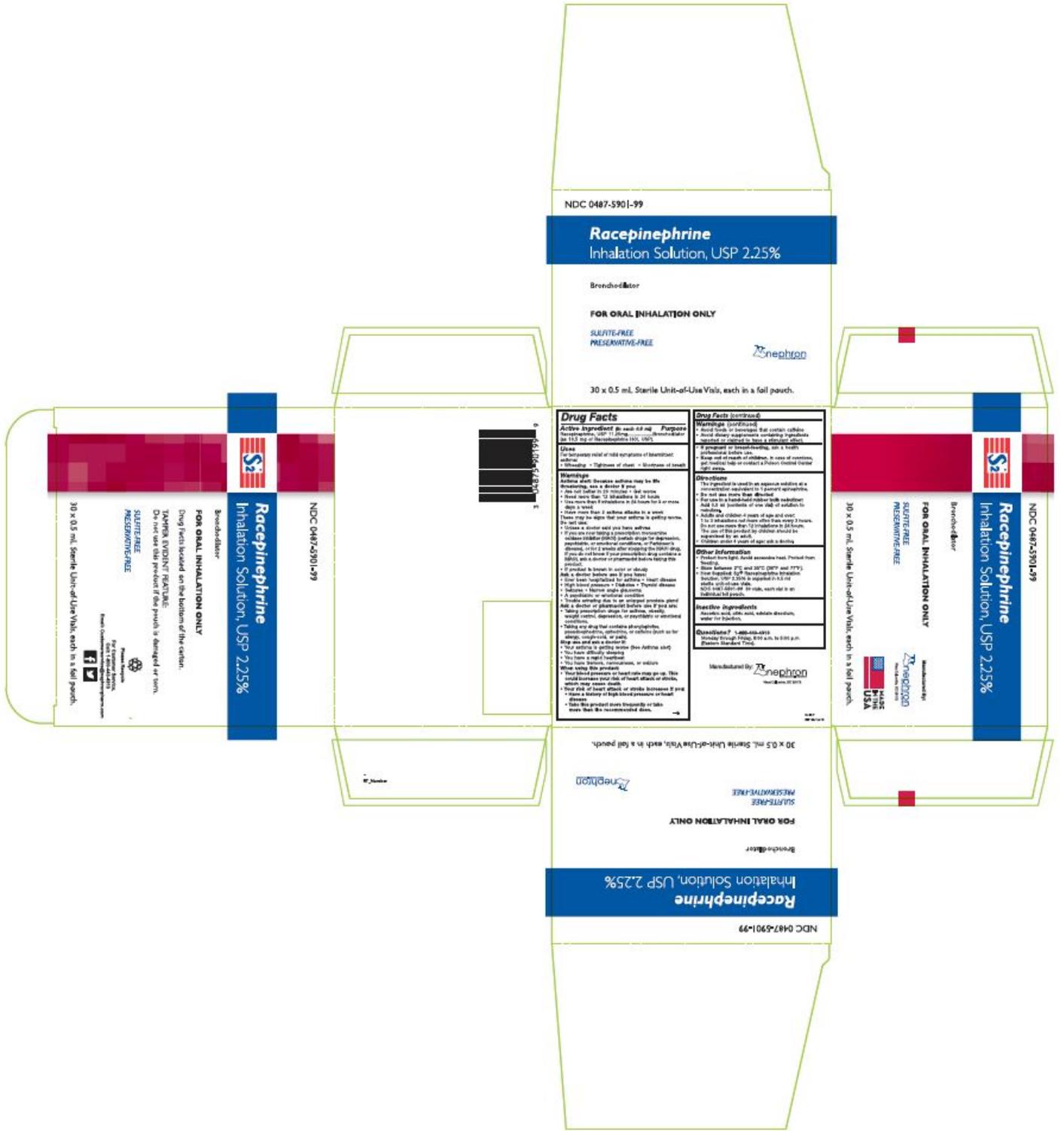
LOT#/EXP.:

Manufactured By:

**nephron**  
pharmaceuticals corporation  
West Columbia, SC 29172  
For Customer Service,  
Call 1-800-443-4313  
IC # 405  
Rev. 10-04-17

Principle Display - Carton (30 Individually Wrapped Vials)

NDC 0487-5901-99



S2  
 racepinephrine hydrochloride solution

**Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0487-5901

Route of Administration

RESPIRATORY (INHALATION)

**Active Ingredient/Active Moiety**

Ingredient Name

Basis of Strength

Strength

|  |                |                    |
|--|----------------|--------------------|
| RACEPINEPHRINE HYDROCHLORIDE (UNII: 336096P2WE) (RACEPINEPHRINE - UNII:GR0L9S3J0F) | RACEPINEPHRINE | 11.25 mg in 0.5 mL |
|--|----------------|--------------------|

### Inactive Ingredients

| Ingredient Name                            | Strength |
|--|----------|
| ASCORBIC ACID (UNII: PQ6CK8PD0R)           |          |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) |          |
| EDETATE DISODIUM (UNII: 7FLD91C86K)        |          |
| WATER (UNII: 059QF0KO0R)                   |          |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0487-5901-99 | 30 in 1 CARTON  | 01/01/2000           |                    |
| 1 |                  | 1 in 1 POUCH  |                      |                    |
| 1 |                  | 0.5 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341                                  | 01/01/2000           |                    |

**Labeler** - Nephron SC, Inc. (079160190)

### Establishment

| Name             | Address | ID/FEI    | Business Operations   |
|------------------|---------|-----------|---|
| Nephron SC, Inc. |         | 079160190 | manufacture(0487-5901) , analysis(0487-5901) , pack(0487-5901) , label(0487-5901) |

Revised: 1/2021

Nephron SC, Inc.