**S2 RACEPINEPHRINE MULTI-DOSE- racepinephrine hydrochloride solution**
**Nephron SC, Inc.**

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**Racepinephrine Inhalation Solution, USP 2.25% (For Export Only)**

***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.

**Allergy alert**

Contains potassium metabisulfite and sodium metabisulfite, sulfites that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

**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**

- **Do not use more than directed**
- The ingredient is used in an aqueous solution at a concentration equivalent to 1 percent epinephrine.
- **For use in a nebulizer:**
  Add 0.5 ml (approximately 10 drops) of solution to nebulizer.
- Adults and children 4 years of age and over:
  1 to 3 inhalations not more often than every 3 hours. Start with one inhalation, then wait at least 1 minute. If symptoms do not improve, use once more. Do not exceed more than 3 inhalations over a 3 hour period.
  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 2® Racepinephrine Inhalation Solution, 2.25% is supplied in 15 ml amber glass, multi-dose bottles.
  NDC 0487-5910-01 15 ml amber glass, multi-dose bottle

**Inactive Ingredients**

Benzoic acid, chlorobutanol, potassium metabisulfite, propylene glycol, sodium chloride, sodium metabisulfite, 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

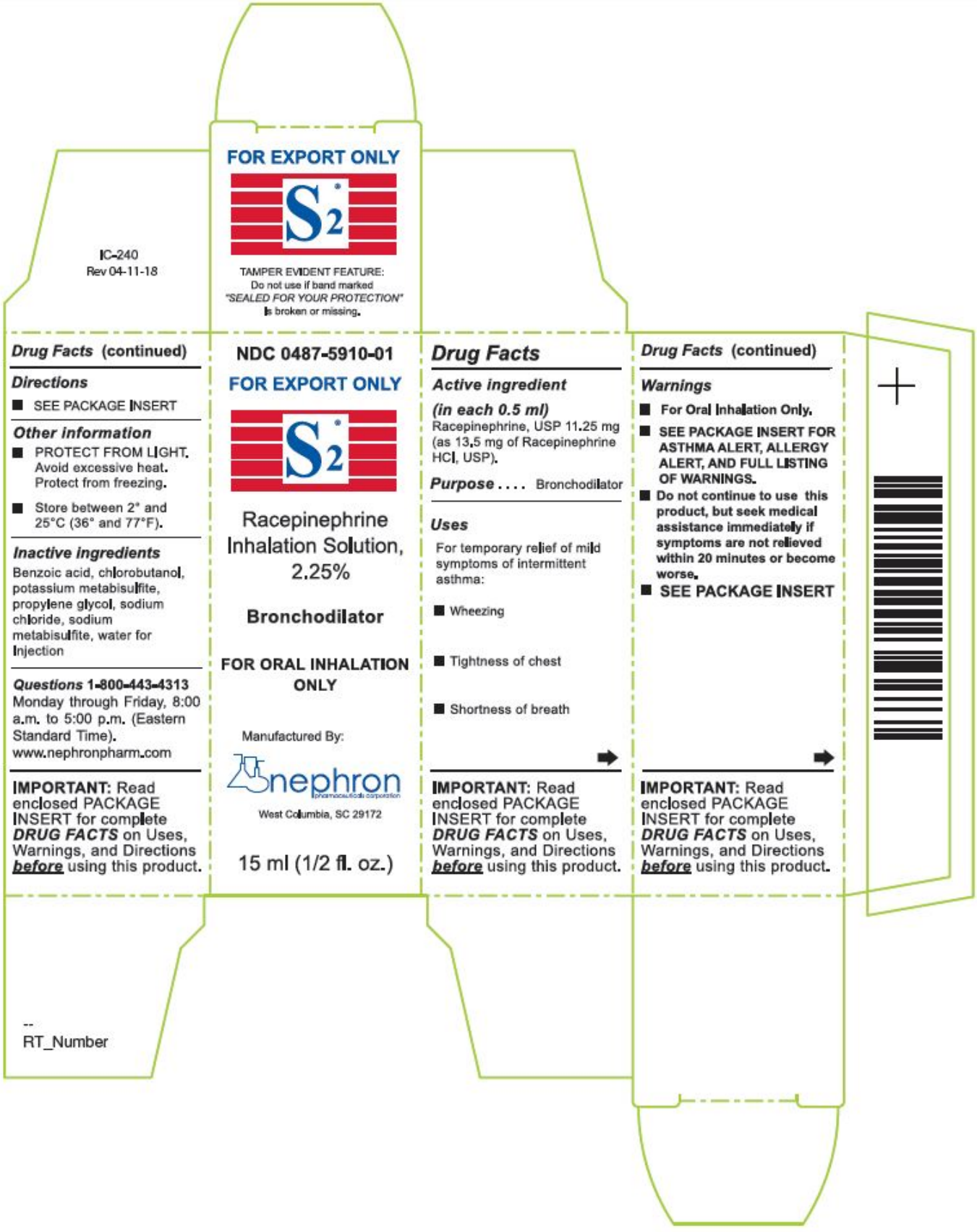
**PRINCIPAL DISPLAY PANEL - 15 ml Bottle**

**Principal Dispay - Primary Container Label (15 mL Amber Glass, Multi-Dose Bottle)**

**NDC 0487-5910-01**


**Principal Display - Carton (Individual 15 mL Amber Glass, Multi-Dose Bottle)**

**NDC 0487-5910-01**




# S2 RACEPINEPHRINE MULTI-DOSE

racepinephrine hydrochloride solution

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0487-5910 |
| **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 |
|---|---|
| **BENZOIC ACID** (UNII: 8SKN0B0MIM) | |
| **CHLOROBUTANOL** (UNII: HM4YQM8WRC) | |
| **POTASSIUM METABISULFITE** (UNII: 65OE787Q7W) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) | |
| **SODIUM METABISULFITE** (UNII: 4VON5FNS3C) | |
| **WATER** (UNII: 059QF0KO0R) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0487-5910-01 | 1 in 1 CARTON | 08/12/1992 | |
| **1** | | 15 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| Export only | | 08/12/1992 | |

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

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Nephron SC, Inc. | | 079160190 | manufacture(0487-5910) , analysis(0487-5910) , pack(0487-5910) , label(0487-5910) |