

S2- racepinephrine hydrochloride solution
Nephron SC, 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.

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: S₂[®] 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

**Racepinephrine
Inhalation Solution,
USP 2.25%**



FOR ORAL INHALATION ONLY

Drug Facts

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



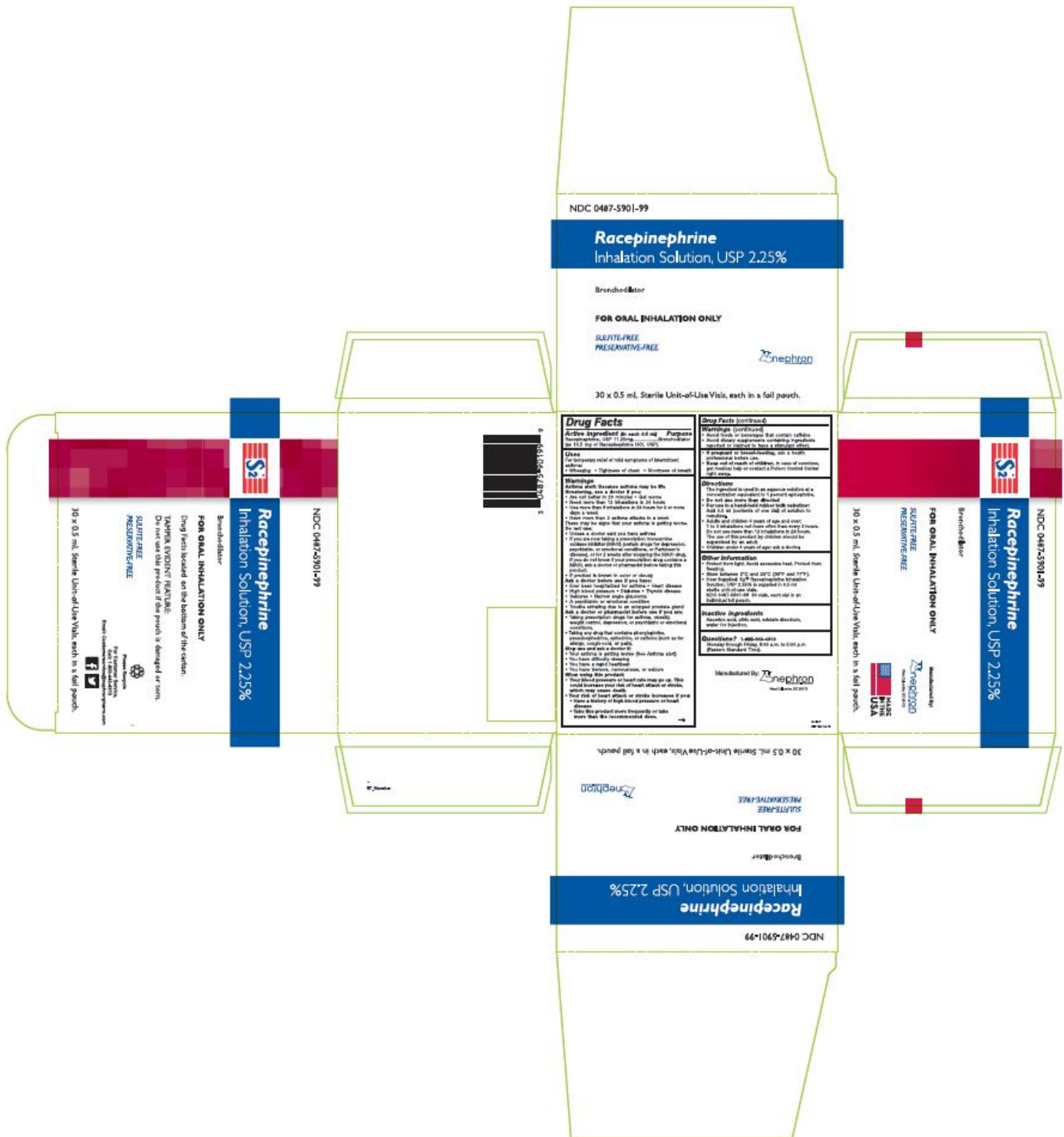
West Columbia, SC 29172
For Customer Service,
Call 1-800-443-4313

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: 059QF0K00R)				
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.