

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

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: S₂[®] 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 Display - Primary Container Label (15 mL Amber Glass, Multi-Dose Bottle)

NDC 0487-5910-01

USES: SEE PACKAGE INSERT. For temporary relief of mild symptoms of intermittent asthma: • Wheezing •Tightness of chest •Shortness of breath.

Warnings: SEE PACKAGE INSERT FOR ASTHMA ALERT, ALLERGY ALERT, AND FULL LISTING OF WARNINGS.

Directions: SEE PACKAGE INSERT.

IMPORTANT: Read enclosed PACKAGE INSERT for complete **Drug Facts** on Uses, Warnings, and Directions before using this product.



West Columbia, SC 29172

NDC 0487-5910-01
FOR EXPORT ONLY



Racepinephrine
Inhalation Solution,
2.25%

(Bronchodilator)

FOR ORAL INHALATION ONLY

15 mL (1/2 fl. oz.)

TAMPER EVIDENT FEATURE:
DO NOT USE IF BAND MARKED
"SEALED FOR YOUR PROTECTION"
IS BROKEN OR MISSING.

ACTIVE INGREDIENT
(in each 0.5 ml):
Racepinephrine, USP 11.25 mg
(as 13.5 mg Racepinephrine
HCl, USP).
Purpose.....Bronchodilator

INACTIVE INGREDIENTS:
Benzoic acid, chlorobutanol,
potassium metabisulfite,
propylene glycol, sodium
chloride, sodium
metabisulfite, water for
injection.

PROTECT FROM LIGHT.
Store between 2° and 25°C
(36° and 77°F).
Avoid excessive heat.
Protect from freezing.

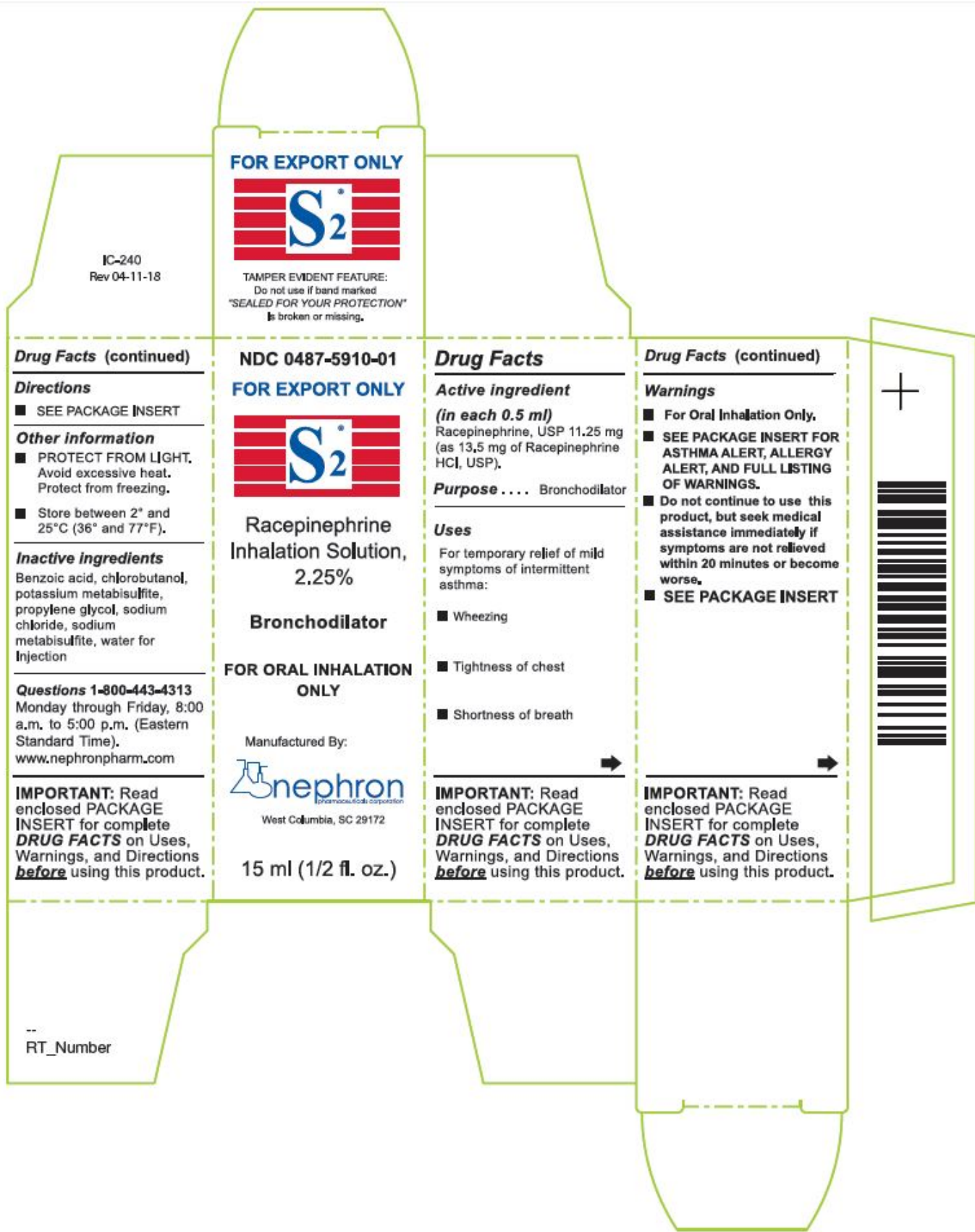
Rev 03-23-18
IC 200

Exp. Date:

Lot:

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

NDC 0487-5910-01



IC-240
Rev 04-11-18

FOR EXPORT ONLY



TAMPER EVIDENT FEATURE:
Do not use if band marked
"SEALED FOR YOUR PROTECTION"
is broken or missing.

Drug Facts (continued)

Directions

- SEE PACKAGE INSERT

Other information

- PROTECT FROM LIGHT. Avoid excessive heat. Protect from freezing.

- Store between 2° and 25°C (36° and 77°F).

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).
www.nephronpharm.com

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NDC 0487-5910-01

FOR EXPORT ONLY



Racepinephrine
Inhalation Solution,
2.25%

Bronchodilator

FOR ORAL INHALATION
ONLY

Manufactured By:



West Columbia, SC 29172

15 ml (1/2 fl. oz.)

Drug Facts

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(in each 0.5 ml)
Racepinephrine, USP 11.25 mg
(as 13.5 mg of Racepinephrine HCl, USP).

Purpose Bronchodilator

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Drug Facts (continued)

Warnings

- For Oral Inhalation Only.
- SEE PACKAGE INSERT FOR ASTHMA ALERT, ALLERGY ALERT, AND FULL LISTING OF WARNINGS.
- Do not continue to use this product, but seek medical assistance immediately if symptoms are not relieved within 20 minutes or become worse.
- SEE PACKAGE INSERT

IMPORTANT: Read enclosed PACKAGE INSERT for complete **DRUG FACTS** on Uses, Warnings, and Directions **before** using this product.

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RT_Number

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: 650E787Q7W)				
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)