NEBUCLEAR MD- racepinephrine liquid Blue Echo Care LLC

Active ingredient

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

Warning

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 with a Jet or Ultrasonic 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

Storage and Handling

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

How Supplied: NebuClear MD® Racepinephrine Inhalation Solution, USP 2.25% is

supplied in 0.5 mL sterile vials. 30 vials, each vial in an individual pouch.

Inactive Ingredients

Ascorbic acid, citric acid, edetate disodium, water.

Questions

1 (855) 860-3404

support@blueechocare.com

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

Manufactured By:

Blue Echo Care LLC 3639 SE 21st Ave

Portland, OR 97202 USA

PRINCIPAL DISPLAY PANEL - 0.5 mL Vial Carton

Contains 30 NebuClear MD® Racepinephine vials

Racepinephine

Racepinephrine Inhalation Solution Bronchodilator

FOR TEMPORARY RELIEF

OF MILD SYMPTOMS OF

INTERMITTENT ASTHMA

- Shortness of breath
- Tightness of chest
- Wheezing

Important: Do not exceed recommended dose.



NEBUCLEAR MD

racepinephrine liquid

| Product Information | | | |
|-------------------------|--------------------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73117-519 |
| Route of Administration | RESPIRATORY (INHALATION) | | |
| | | | |

Active Ingredient/Active Moiety Ingredient Name Basis of Strength RACEPINEPHRINE HYDROCHLORIDE (UNII: 336096P2WE) (EPINEPHRINE,(+/-)UNII:GROL9S3J0F) EPINEPHRINE,(+/-)In 11.25 mg in 0.5 mL

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

| ı | Packaging | | | | |
|---|-----------|----------------------|--|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 | NDC:73117-519- 17 | 30 mL in 1 CARTON; Type 0: Not a Combination Product | 05/20/2025 | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M012 | 05/20/2025 | |
| | | | |

Labeler - Blue Echo Care LLC (117048847)

| Establishment | | | | |
|--------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Blue Echo Care LLC | | 117048847 | manufacture(73117-519) | |

Revised: 5/2025 Blue Echo Care LLC