

EPI-MIST- racepinephrine hydrochloride aerosol, spray
DRNATURALHEALING 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.

Prime Asthma Relief EpiMist

ACTIVE INGREDIENT

ACTIVE INGREDIENT: Racepinephrine HCL, USP (1% Epinephrine)

PURPOSE

BRONCHODILATOR

INDICATIONS AND USAGE

DRUG FACTS

ACTIVE INGREDIENT

Racinephrine HCl, USP (1% Epinephrine)

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 taken 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 an 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
- high blood pressure
- thyroid disease
- narrow angle glaucoma
- trouble urinating due to an enlarged prostate gland.
- heart disease
- diabetes
- seizures
- a psychiatric or emotional condition

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).

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.

INACTIVE INGREDIENTS:

Water, Ascorbic Acid, Edetate Disodium, Citric Acid, Polysorbate-60. All USP grade.

- Your risk of heart attack or stroke increases if you:
 - (1) have a history of high blood pressure or heart disease
 - (2) 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.

Stop use and ask a doctor if:

- your asthma is getting worse (see Asthma Alert)
- you have difficulty sleeping
- you have a rapid heart beat
- you have tremors, nervousness, seizure

IF PREGNANCY OR BREAST FEEDING: ask a health professional for advice 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 take more than directed.**
- Squeeze-inhale at the same time. For detail, please read User Guide.
- Adults and children 4 years of age and over: 1 inhalation at one time.
- Do not use more than once every 3 hours. Do not use more than 12 inhalations in 24 hours.
- Use of this product by children should be supervised by an adult.
- Children under 4 years of age: Please ask a doctor for help.

WARNING SECTION

DRUG FACTS

ACTIVE INGREDIENT

Racinephrine HCl, USP (1% Epinephrine)

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 taken 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 an 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
- high blood pressure
- thyroid disease
- narrow angle glaucoma
- trouble urinating due to an enlarged prostate gland.
- heart disease
- diabetes
- seizures
- a psychiatric or emotional condition

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).

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.

INACTIVE INGREDIENTS:

Water, Ascorbic Acid, Edetate Disodium, Citric Acid, Polysorbate-60. All USP grade.

- Your risk of heart attack or stroke increases if you:
 - (1) have a history of high blood pressure or heart disease
 - (2) 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.

Stop use and ask a doctor if:

- your asthma is getting worse (see Asthma Alert)
- you have difficulty sleeping
- you have a rapid heart beat
- you have tremors, nervousness, seizure

IF PREGNANCY OR BREAST FEEDING: ask a health professional for advice 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 take more than directed.**
- Squeeze-inhale at the same time. For detail, please read User Guide.
- Adults and children 4 years of age and over: 1 inhalation at one time.
- Do not use more than once every 3 hours. Do not use more than 12 inhalations in 24 hours.
- Use of this product by children should be supervised by an adult.
- Children under 4 years of age: Please ask a doctor for help.

DOSAGE AND ADMINISTRATION

DIRECTIONS

- Do not take more than directed
- Place your lips around the mouthpiece and squeeze the bulb while inhaling simultaneously to breathe in the epinephrine aerosol— see figure below for details
- Adults and children 4 years of age and over: Do not take more than one dose every 3 hours. Do not take more than 8 doses in a 24-hour period. The use of this product by children under the age of 12 should be supervised by an adult.
- For children's usage between 4 to 12 years of age: an adult may squeeze the bulb while your child inhales.
- Please contact your doctor if your symptoms advance.

How Supplied

HOW SUPPLIED

Each unit of EpiMist contains 10 ml, 250 doses of epinephrine. Each dose (40 microliters) is delivered by one (1) turn-click of the device, containing 1% epinephrine solution made with racepinephrine hydrogen chloride, USP.

Storage and Handling

STORAGE AND HANDLING

- 1) Protect from light to reduce loss of the activity of the active ingredient.
- 2) Avoid excessive heat.
- 3) You can carry the whole set during daytime but avoid excessive heat and bright light.
- 4) When at home, it is recommended to store in refrigerator (35 to 40 oF).
- 5) After the liquid medicine is used out, dispose the plastic device properly.

Inactive Ingredient Section

INACTIVE INGREDIENT

Water, Edetate Disodium, Ascorbic Acid, Citric Acid, Polysobate-60. All USP grade.

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away

DISPLAY PANEL

EPINEPHRINE MIST



Prime Asthma Relief

EpiMist



Temporary Relief
of Mild Symptoms
of Intermittent Asthma:

- *Wheezing*
- *Tightness of Chest*
- *Shortness of Breath*

Epinephrine Mist

*Oral inhalation via
Hand-Held Rubber Bulb Nebulizer
Asthma OTC Monograph*

**250
Doses**

NDC: 15343-125-22

To Relieve Asthma Symptoms

***Squeeze
Inhale
Breathe***

- Affordable 250 Doses
- Fast Acting
- Easy Oral Inhalation
- Does Not Clog
- No Batteries Needed
- Easy to Maintain
- Carrying Case Included
- Light Weight, 2 Oz
- Patent Pending

Questions & Comments?

888-658-8108

info@DrNaturalHealing.com
www.DrNaturalHealing.com

Manufactured for:

DrNaturalHealing, Inc.
111 McCoy Street
Milford, DE 19963, USA

©2015 DrNaturalHealing, Inc.



EPINEPHRINE MIST

NDC: 15343-125-22



Prime Asthma Relief

EpiMist



Temporary Relief
of Mild Symptoms
of Intermittent Asthma:

- Wheezing
- Tightness of Chest
- Shortness of Breath

Epinephrine Mist
Oral inhalation via
Hand-Held Rubber Bulb Nebulizer
Asthma OTC Monograph

**250
Doses**

To Relieve Asthma Symptoms

**Squeeze
Inhale
Breathe**

- Affordable 250 Doses
- Fast Acting
- Easy Oral Inhalation
- Does Not Clog
- No Batteries Needed
- Easy to Maintain
- Carrying Case Included
- Light Weight, 2 Oz
- Patent Pending

Questions & Comments?

888-658-8108

info@DrNaturalHealing.com
www.DrNaturalHealing.com

Manufactured for:
DrNaturalHealing, Inc.
111 McCoy Street
Milford, DE 19963, USA
©2015 DrNaturalHealing, Inc.



EPI-MIST

racepinephrine hydrochloride aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:15343-125
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

RACEPINEPHRINE HYDROCHLORIDE (UNII: 336096P2WE) (RACEPINEPHRINE - UNII:GR0L9S3J0F)	RACEPINEPHRINE	.594 mg in .120 mL
---	----------------	-----------------------

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	.11808 mL in .120 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	1.08 mg in .120 mL
SODIUM CITRATE (UNII: 1Q73Q2JULR)	.120 mg in .120 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	.140 mg in .120 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15343-125-22	1 in 1 KIT	03/15/2018	
1		15 mL in 1 INHALER; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/15/2015	

Labeler - DRNATURALHEALING INC (129613308)

Registrant - DRNATURALHEALING INC (129613308)

Establishment

Name	Address	ID/FEI	Business Operations
NEW LIFE RESOURCES		169822900	manufacture(15343-125)

Revised: 3/2018

DRNATURALHEALING INC