

Primatene[®] MIST

Epinephrine Inhalation Aerosol

The #1 **over-the-counter** medicine sold for the relief of physician-diagnosed, bronchial asthma.

“easy and effective”

- **Fast-Acting Asthma Relief**
- **Available without a prescription.**
- **Asthma relief that starts in as fast as 15 seconds.**
- **Can be used at any time of the day or night as directed.**
- **Available in most major food, drug and mass merchandise retailers across the U.S.**



Primatene[®] Mist is available in:

NEW UPC #

- 1/2 fl oz (15 mL) with mouthpiece (actuator)..... 317270-503002
- 1/2 fl oz (15 mL) refill..... 317270-504009

01-801-02
10/08



Armstrong Pharmaceuticals, Inc.
423 LaGrange Street
West Roxbury, MA 02132
1-8PRIMATENE or 1-877-462-8363

Primatene[®] MIST

For the Temporary Relief of
BRONCHIAL ASTHMA

Drug Facts

Active ingredient (in each inhalation)

Epinephrine 0.22 mg.....Bronchodilator

Purpose

Uses

■ for temporary relief of occasional symptoms of mild asthma:

- wheezing
- tightness of chest
- shortness of breath

Warnings

Asthma alert: Because asthma can be life threatening, see a doctor if you

- are not better in 20 minutes
- get worse
- need 12 inhalations in any day
- use more than 9 inhalations a day for more than 3 days a week
- have more than 2 asthma attacks in a week

For inhalation only

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.

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)

When using this product

- increased blood pressure or heart rate can occur, which could lead to more serious problems such as heart attack and stroke. Your risk may increase if you take more frequently or more than the recommended dose.
- nervousness, sleeplessness, rapid heart beat, tremor, and seizure may occur. If these symptoms persist or get worse, consult a doctor right away.
- avoid caffeine-containing foods or beverages.
- avoid dietary supplements containing ingredients reported or claimed to have a stimulant effect.
- do not puncture or throw into incinerator. Contents under pressure.
- do not use or store near open flame or heat above 120°F (49°C). May cause bursting.

Contains CFC 12, 114, substances which harm public health and environment by destroying ozone in the upper atmosphere.

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 exceed dosage
- supervise children using this product
- adults and children 4 years and over: start with one inhalation, then wait at least 1 minute. If not relieved, use once more. Do not use again for at least 3 hours.
- children under 4 years of age: ask a doctor

Other information

- store at room temperature, between 20-25°C (68-77°F)
- contains no sulfites
- see insert for mouthpiece use and care instructions

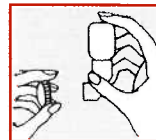
Inactive ingredients ascorbic acid, dehydrated alcohol (34%), dichlorodifluoromethane (CFC 12), dichlorotetrafluoroethane (CFC 114), hydrochloric acid, nitric acid, purified water

Intentional abuse of this product can be harmful or fatal.

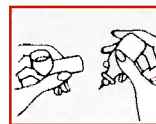
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DIRECTIONS FOR USE OF MOUTHPIECE-- The Primatene[®] Mist mouthpiece, which is enclosed in the Primatene[®] Mist 15 mL size (not the refill size), should be used for inhalation only with Primatene[®] Mist.

1. Take plastic cap off mouthpiece.
(For refills, use mouthpiece from previous purchase.)



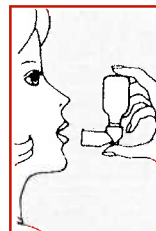
2. Take plastic mouthpiece off bottle.



3. Place short end of mouthpiece on bottle.



4. Turn bottle upside down. Place thumb on bottom of mouthpiece over circular button and forefinger on top of vial. Empty the lungs as completely as possible by exhaling.



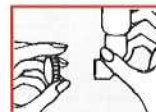
5. Place mouthpiece in mouth with lips closed around opening. Inhale deeply while squeezing mouthpiece and bottle together. Release immediately and remove unit from mouth, then complete taking the deep breath, drawing medication into your lungs, holding breath as long as comfortable.



6. Exhale slowly keeping lips nearly closed. This helps distribute the medication in the lungs.



7. For storage, place long end of mouthpiece back on bottle and cover with plastic cap.



CARE OF THE MOUTHPIECE The Primatene[®] Mist mouthpiece should be washed after each use with hot, soapy water, rinsed thoroughly, and dried with a clean, lint-free cloth.

If the unit becomes clogged and fails to spray, please write and send the clogged unit to: Armstrong Pharmaceuticals, Inc., 423 La Grange Street, West Roxbury, MA 02132

Questions or comments? call 1-8 PRIMATENE or 1-877-462-8363

ARMSTRONG
Pharmaceuticals, Inc.