

**PRIMATENE MIST- epinephrine inhalation aerosol**  
**Armstrong Pharmaceuticals, Inc.**

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**Active ingredient (in each spray)**

Epinephrine 0.125 mg

**Purpose**

Bronchodilator

**Uses**

for temporary relief of mild symptoms of intermittent asthma

- wheezing
- tightness of chest
- shortness of breath

**Warnings**

**For oral inhalation only**

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

- are not better in 20 minutes
- get worse
- need more than 8 inhalations in 24 hours
- 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 a pharmacist before taking this product.

**Ask a doctor before use if you have**

- ever been hospitalized for asthma
- heart disease
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- thyroid disease
- seizures
- narrow angle glaucoma

## **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.**
- **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
- avoid spraying in eyes
- contents under pressure. Do not puncture or incinerate.
- do not store near open flame or heat above 120°F (49°C). May cause bursting.

## **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, or seizure

**If pregnant or breast-feeding**, ask a health care 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**

- read the Consumer Information Insert for detailed directions on how to use this product
- **do not use more than directed**

- for adults and children 12 years of age and over
- children under 12 years of age: do not use; it is not known if the drug works or is safe in children under 12

## **Before first use (new inhaler)**

activate new inhaler by shaking then spraying into air 4 separate times

## **each time you dose**

- remove red cap (if attached)
- shake then spray into the air 1 time
- exhale completely, place inhaler in mouth
- inhale deeply while pressing down on top of inhaler, then continue the deep breath
- hold breath as long as possible, exhale

■ wait 1 minute. If symptoms not relieved, take a second inhalation by repeating steps above.

#### **after use**

■ wait at least **4 hours between doses**

■ do not use more than **8 inhalations in 24 hours**

■ wash inhaler after each day of use. Run water through the mouthpiece for 30 seconds.

#### **Other information**

■ store at room temperature, between 15-25°C (59-77°F)

■ contains no sulfites

■ keep this label and enclosed materials. They contain important additional information.

#### **Inactive ingredients**

dehydrated alcohol (1%), hydrofluoroalkane (HFA 134a), polysorbate 80, thymol

#### **Questions or comments?**

call **1-8 Primatene** or **1-877-462-8363**

Mon.- Fri. 7 am - 5 pm PST

#### **Primatene MIST® Carton**

#### **Principal Display Panel Text:**

**Primatene MIST®**

**Epinephrine Inhalation Aerosol**

**0.125 mg per spray**

**Bronchodilator**

**For Oral**

**Inhalation Only**

**For TEMPORARY relief**

**of MILD symptoms**

**of INTERMITTENT asthma**

Suspension:

**Shake then Spray**

into the air before

each inhalation.

**This item is**

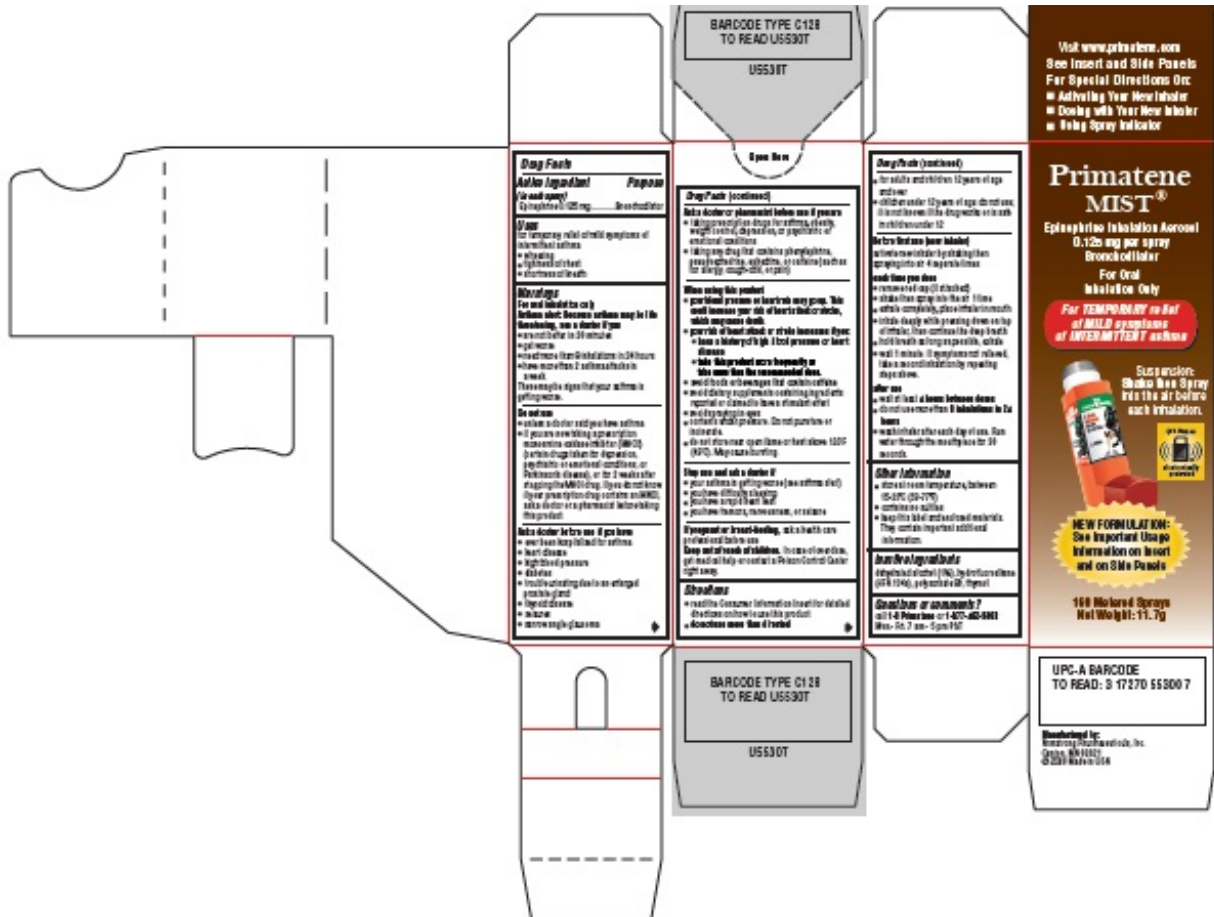
**electronically**

**protected**

**NEW FORMULATION:**

**See Important Usage Information on Insert and on Side Panels**

**160 Metered Sprays  
Net Weight: 11.7g**



**PRIMATENE MIST**

epinephrine inhalation aerosol

**Product Information**

|                                |                          |                           |                |
|--------------------------------|--------------------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG           | <b>Item Code (Source)</b> | NDC:17270-5530 |
| <b>Route of Administration</b> | RESPIRATORY (INHALATION) |                           |                |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength |
|--|-------------------|----------|
| EPINEPHRINE (UNII: YKH834O4BH) (EPINEPHRINE - UNII:YKH834O4BH) | EPINEPHRINE       | 125 ug   |

**Inactive Ingredients**

| Ingredient Name               | Strength |
|-------------------------------|----------|
| ALCOHOL (UNII: 3K9958V90M)    |          |
| NORFLURANE (UNII: DH9E53K1Y8) |          |

**POLYSORBATE 80** (UNII: 6OZP39ZG8H)

**THYMOL** (UNII: 3J50XA376E)

### Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:17270-5530-0 | 1 in 1 CARTON  | 12/14/2018           |                    |
| 1 |                  | 160 in 1 INHALER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.) |                      |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA                | NDA205920                                | 12/14/2018           |                    |

**Labeler** - Armstrong Pharmaceuticals, Inc. (809773794)

### Establishment

| Name                            | Address | ID/FEI    | Business Operations                            |
|---------------------------------|---------|-----------|--|
| Armstrong Pharmaceuticals, Inc. |         | 809773794 | manufacture(17270-5530) , analysis(17270-5530) |

Revised: 6/2024

Armstrong Pharmaceuticals, Inc.