

PRIMATENE MIST- epinephrine inhalation aerosol
Armstrong Pharmaceuticals, Inc.

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

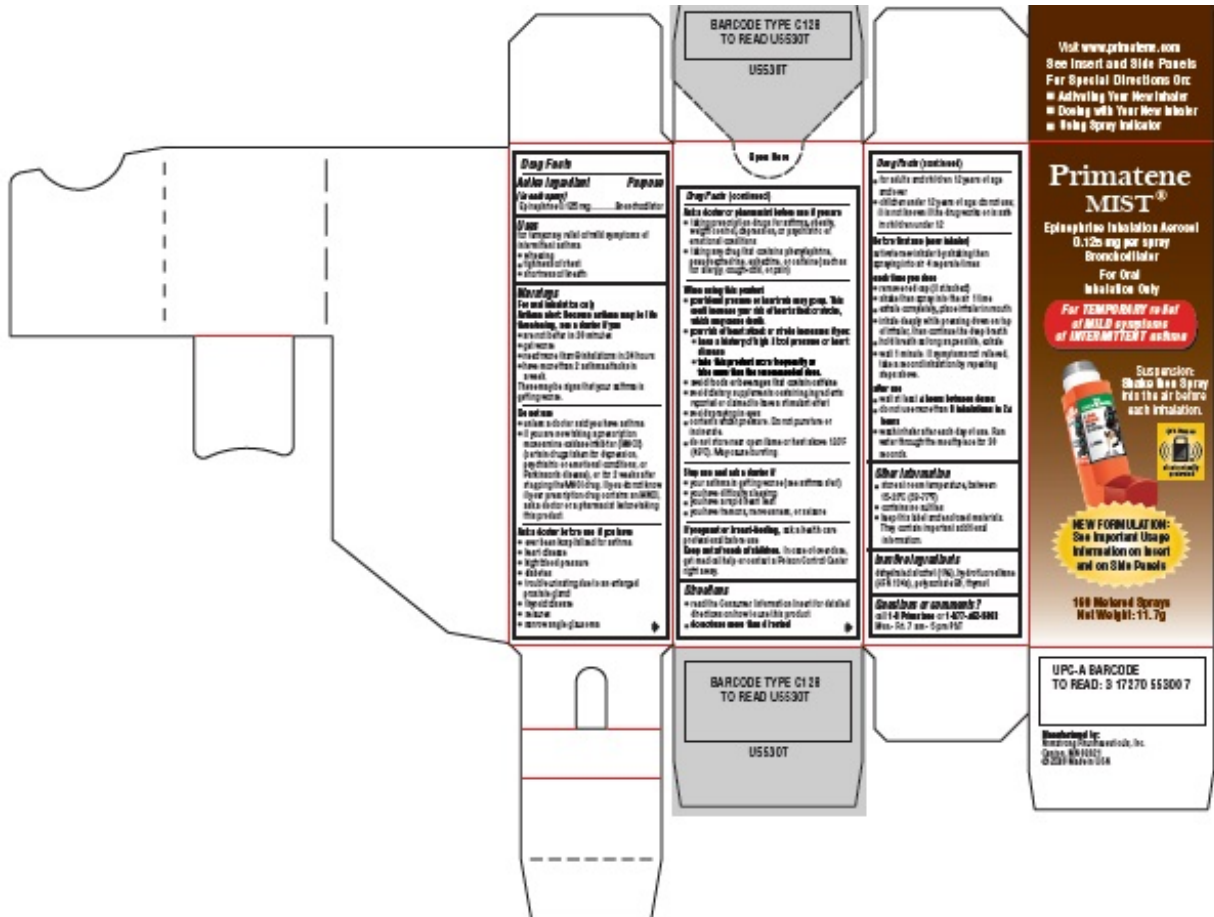
electronically

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17270-5530
Route of Administration	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: 7/2020

Armstrong Pharmaceuticals, Inc.