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...
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® 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.

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

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:17270-553</th>
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<tbody>
<tr>
<td>Route of Administration</td>
<td>RESPIRATORY (INHALATION)</td>
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## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>EPINEPHRINE</td>
<td>EPINEPHRINE</td>
<td>125 ug</td>
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## Inactive Ingredients

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<th>Ingredient Name</th>
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<tbody>
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<td>ALCOHOL</td>
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</tr>
<tr>
<td>NORFLURANE</td>
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</tr>
<tr>
<td>POLYSORBATE 80</td>
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<tr>
<td>THYMOL</td>
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## Packaging

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<th>Marketing End Date</th>
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<tr>
<td>1</td>
<td></td>
<td>160 in 1 INHALER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)</td>
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## Marketing Information

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<th>Application Number or Monograph Citation</th>
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## Labeler

- Armstrong Pharmaceuticals, Inc. (809773794)

## Establishment

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<th>ID/FEI</th>
<th>Business Operations</th>
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<tr>
<td>Armstrong Pharmaceuticals, Inc.</td>
<td>809773794</td>
<td>manufacture(17270-553), analysis(17270-553), pack(17270-553)</td>
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Revised: 12/2018

Armstrong Pharmaceuticals, Inc.