

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205920Orig1s000

LABELING

BARCODE TYPE C128
TO READ U5530R

U5530R

Open Here

Drug Facts

Active ingredient **Purpose**
(in each spray)
Epinephrine 0.125 mg.....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

Drug Facts (continued)

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

Drug Facts (continued)

- 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

Visit www.primatene.com
See Insert and Side Panels
For Special Directions On:

- Activating Your New Inhaler
- Dosing with Your New Inhaler
- Using Spray Indicator

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

BARCODE TYPE C128
TO READ U5530R

U5530R

UPC-A BARCODE
TO READ: 3 17270 55300 7

Manufactured by:
Armstrong Pharmaceuticals, Inc.
Canton, MA 02021
© 2018 Made in USA

300%

NON
VARNISHED
AREA

LOT:

EXP:

Armstrong Pharmaceuticals, Inc. Canton, MA 02021

Active Ingredient (in each spray) Epinephrine 0.125 mg

Use: for temporary relief of mild symptoms of intermittent asthma: wheezing, tightness of chest, shortness of breath.

Warnings: Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. **Stop use and ask a doctor if:** your asthma is getting worse, you have difficulty sleeping, you have a rapid heart beat, you have tremors, nervousness, or seizure. **Directions:** Do not use more than directed. Adults and children 12 years of age and over: **shake then spray** into the air one time before each inhalation. **1 to 2 inhalations** for each dose. Start with one inhalation, wait at least 1 minute. If not relieved, **shake then spray** into the air one time and take a second inhalation. Wait at least **4 hours between doses.** Do not use more than **8 inhalations in 24 hours.** Children under 12 years of age: **DO NOT USE.**

Other Information: store at room temperature, between 15-25°C (59-77°F), contains no sulfites, see mouthpiece use/care instructions. **Contains:** dehydrated alcohol (1%), hydrofluoroalkane (HFA-134a), polysorbate 80, thymol

Questions or Comments? Call **1-(877)-462-8363**

See consumer information insert and outer carton for detailed directions.

**Primatene®
MIST**

**Epinephrine Inhalation
Aerosol
0.125 mg per spray
Bronchodilator**

For Oral Inhalation **Only**
With Primatene® Mist
Mouthpiece

L5530H

100%

NON
VARNISHED
AREA

LOT:

EXP:

Armstrong Pharmaceuticals, Inc. Canton, MA 02021

Active Ingredient (in each spray) Epinephrine 0.125 mg

Use: for temporary relief of mild symptoms of intermittent asthma: wheezing, tightness of chest, shortness of breath.

Warnings: Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. **Stop use and ask a doctor if:** your asthma is getting worse, you have difficulty sleeping, you have a rapid heart beat, you have tremors, nervousness, or seizure. **Directions:** Do not use more than directed. Adults and children 12 years of age and over: **shake then spray** into the air one time before each inhalation. **1 to 2 inhalations** for each dose. Start with one inhalation, wait at least 1 minute. If not relieved, **shake then spray** into the air one time and take a second inhalation. Wait at least **4 hours between doses.** Do not use more than **8 inhalations in 24 hours.** Children under 12 years of age: **DO NOT USE.**

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Questions or Comments? Call **1-(877)-462-8363**

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**Primatene®
MIST**

**Epinephrine Inhalation
Aerosol
0.125 mg per spray
Bronchodilator**

For Oral Inhalation **Only**
With Primatene® Mist
Mouthpiece

L5530H

L5535A

Activate Before First Use Only	Dose A dose is 1-2 Inhalations	Wash After Each Day of Use
<p>1. Shake </p> <p>2. Test spray into the air </p> <p>You must repeat both actions 4 times.</p>	<p>1. Shake then spray into the air one time </p> <p>2. Inhale </p>	<p>1. Remove red cap and container. </p> <p>2. Run water through mouthpiece for 30 seconds. </p> <p>3. Shake off excess water. </p>

Read Insert Before Use
Visit primatene.com



Please Read These Instructions Carefully. This Inhaler Might Be Different From What You Are Used To.

Primatene[®] MIST

Epinephrine Inhalation Aerosol
0.125 mg per Spray, Bronchodilator

For **TEMPORARY** relief of **MILD** symptoms of **INTERMITTENT** asthma

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.

Important Information

Children under 12 years of age: **DO NOT USE.** It is not known if the drug works or is safe in children under 12.

Maximum daily dose: Do not use more than 8 inhalations in 24 hours.

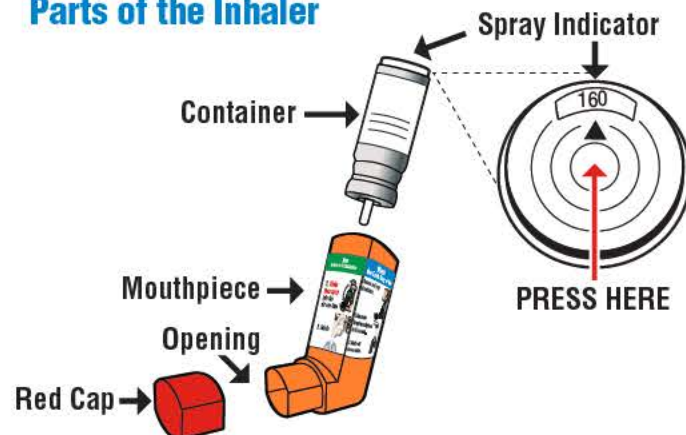
See your doctor if you have more than 2 asthma attacks in a week.

Shake then Spray into the air 1 time before each inhalation.

Important to Know

- ✓ First time you take a new inhaler out of the box, “**Shake then spray** into the air.” Repeat both actions 4 times. See Panel A below.
- ✓ **Shake then Spray** into the air 1 time before each inhalation. See Panel B below.
- ✓ Wash inhaler after each day of use. Run water through the mouthpiece for 30 seconds. See Panel C below.
- ✓ The Primatene[®] MIST mouthpiece should only be used with the Primatene[®] MIST container.
- ✓ It is normal for the mouthpiece to change color over time.

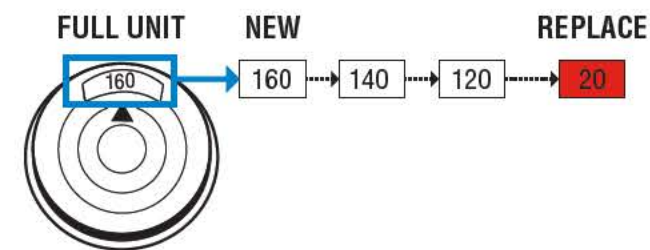
Parts of the Inhaler



Spray Indicator Shows How Many Sprays You Have Left

A full container holds 160 sprays

- After every 20 sprays, the spray indicator number changes.



Starts at 160:
160 Sprays Remaining

Red Zone: Buy a New Inhaler

- Once the red zone appears and the display reads “20,” buy a new inhaler soon.
- The spray indicator will stop counting at “0” and the inhaler must not be used any longer.



Caution

Never try to change the numbers or take the spray indicator off the container.

The spray indicator cannot be reset.

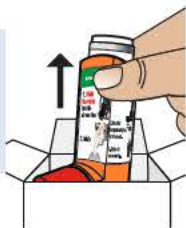
Step-By-Step Instructions

A Activating Your Inhaler

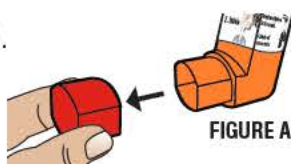
After Opening Box: Before First Use

Activate inhaler before first use.

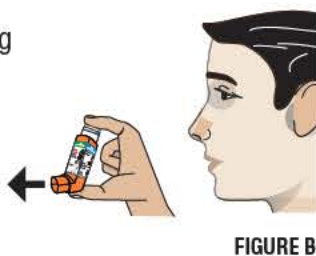
Only do this with a new inhaler, the first time you remove it from the box.



1. Remove red cap (Figure A).



2. Hold inhaler with opening away from your face and others (Figure B).



3. “**Shake then test spray** into the air” (Figure C).

You must repeat both actions 4 times to activate your new inhaler.

Repeat 4 times

SHAKE → **THEN SPRAY INTO THE AIR**

- 1 Shake then Spray
- 2 Shake then Spray
- 3 Shake then Spray
- 4 Shake then Spray



FIGURE C

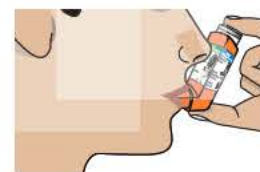
Your Inhaler is Now Ready for Dosing

B Dosing with Your Inhaler

A dose is 1 to 2 inhalations.

For every inhalation: **Shake then Spray** into the Air
→ Inhale → Wait

Follow instructions below.



Shake then Spray into the Air

1. Remove red cap.
2. **Shake then Spray** into the air 1 time to mix the medicine (Figure D).

Shaking and spraying the inhaler are critical.



FIGURE D

Inhale

3. Exhale completely (Figure E).
4. Place mouthpiece in your mouth with your lips closed around the opening.
5. Inhale deeply while pressing down on the center of the spray indicator (top of container) (Figure F). Continue the deep breath.
6. Hold your breath for as long as possible.
7. Release finger and remove inhaler from mouth, then exhale slowly.

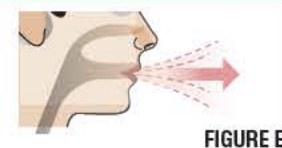


FIGURE E

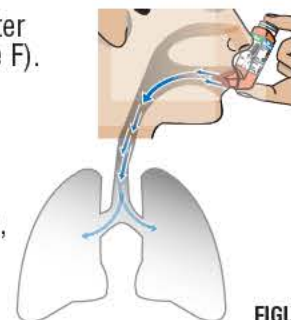


FIGURE F

Wait At Least 1 Minute

8. If symptoms are not relieved after at least 1 minute (Figure G), take a second inhalation by repeating steps 2 to 7 above.



FIGURE G

9. Replace red cap.

C Washing Your Inhaler

Wash your inhaler after each day of use.

Run water through the mouthpiece for 30 seconds after each day of use, as instructed below.

1. Remove red cap (Figure H).

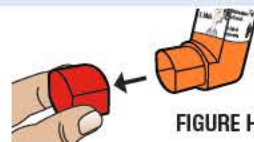


FIGURE H

2. Remove container by firmly grasping and pulling out the container, then set aside (Figure I).



FIGURE I

Don't be afraid to pull hard on the container.

3. Run water through both ends of the mouthpiece for 30 seconds (Figure J).

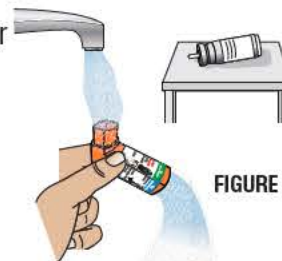


FIGURE J

4. Shake off as much water as you can.

5. Air dry overnight.

6. Put your inhaler back together before next use.

Important: If you need to use when wet, shake off excess water before dosing.

Manufactured by: Armstrong Pharmaceuticals, Inc.,
Canton, MA 02021 © 2018 Made in USA F5530P

www.primatene.com

Section 1.14.2.2
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/s/

THERESA M MICHELE
11/07/2018