

INSTRUCTIONS FOR USE

Arformoterol tartrate inhalation solution is used only in a standard jet nebulizer machine connected to an air compressor. Make sure you know how to use your nebulizer machine before you use it to breathe in arformoterol tartrate inhalation solution or other medicines.

Do not mix arformoterol tartrate inhalation solution with other medicines in your nebulizer machine.

Arformoterol tartrate inhalation solution comes sealed in a foil pouch. Do not open a sealed pouch until you are ready to use a dose of arformoterol tartrate inhalation solution. After opening the pouch, unused unit-dose ampules should be returned to, and stored in, the pouch. An opened unit-dose ampule should be used right away.

1. Open the foil pouch by tearing on the rough edge along the seam of the pouch. Remove a unit-dose ampule of arformoterol tartrate inhalation solution.
2. Carefully twist open the top of the unit-dose ampule and use it right away (Figure 1).

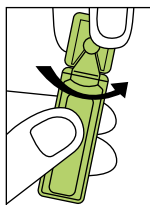


Figure 1

3. Squeeze all of the medicine from the unit-dose ampule into the nebulizer medicine cup (reservoir) (Figure 2).

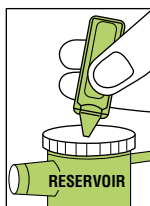


Figure 2

4. Connect the nebulizer reservoir to the mouthpiece (Figure 3) or face mask (Figure 4).

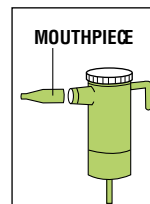


Figure 3



Figure 4

5. Connect the nebulizer to the compressor (Figure 5).

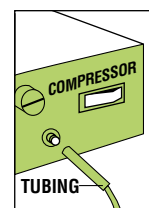


Figure 5

6. Sit in a comfortable, upright position. Place the mouthpiece in your mouth (Figure 6) (or put on the face mask) and turn on the compressor.

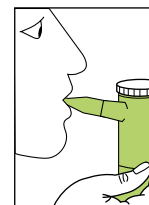


Figure 6

7. Breathe as calmly, deeply, and evenly as possible until no more mist is formed in the nebulizer reservoir. It takes about 5 to 10 minutes for each treatment.

8. Clean the nebulizer (see manufacturer's instructions).

This Instructions for Use has been approved by the Food and Drug Administration.

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PATIENT INFORMATION

Arformoterol Tartrate (ar'' for moe' ter ol tar' trate) Inhalation Solution

What is arformoterol tartrate inhalation solution?

Arformoterol tartrate inhalation solution is for long-term use and should be taken 2 times each day (morning and evening), to help control the symptoms of chronic obstructive pulmonary disease (COPD) for better breathing.

COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both.

Arformoterol tartrate inhalation solution is only for use with a nebulizer.

Long acting beta₂ adrenergic agonist (LABA) medicines, such as arformoterol tartrate inhalation solution, help the muscles around the airways in your lungs stay relaxed to prevent symptoms, such as wheezing, cough, chest tightness, and shortness of breath.

Arformoterol tartrate inhalation solution is not used to treat sudden symptoms of COPD. Always have a short-acting beta₂-agonist medicine (rescue inhaler) with you to treat sudden symptoms of COPD. If you do not have a rescue inhaler, contact your healthcare provider to have one prescribed for you.

Arformoterol tartrate inhalation solution is not for the treatment of asthma. It is not known if arformoterol tartrate inhalation solution is safe and effective in people with asthma.

Arformoterol tartrate inhalation solution should not be used in children. It is not known if arformoterol tartrate inhalation solution is safe and effective in children.

Do not use arformoterol tartrate inhalation solution if you:

are allergic to arformoterol, racemic formoterol, or any of the ingredients in arformoterol tartrate inhalation solution. Ask your healthcare provider if you are not sure. See the end of this leaflet for a complete list of ingredients in arformoterol tartrate inhalation solution.

have asthma.

Before you use arformoterol tartrate inhalation solution, tell your healthcare provider about all of your medical conditions, including if you:

have heart problems
have high blood pressure
have seizures
have thyroid problems
have diabetes
have liver problems
are pregnant or plan to become pregnant. It is not known if arformoterol tartrate can harm your unborn baby.
are breastfeeding or plan to breastfeed. It is not known if the arformoterol or any other ingredients in arformoterol tartrate passes into your milk and if it can harm your baby. You and your healthcare provider should decide if you will take arformoterol tartrate inhalation solution or breastfeed.

Tell your healthcare provider about all the medicines you take including prescription and over-the-counter medicines, vitamins and herbal supplements. Arformoterol tartrate inhalation solution and certain other medicines may interact with each other. This may cause serious side effects. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

How should I use arformoterol tartrate inhalation solution?

Read the step-by-step Instructions for Use for arformoterol tartrate inhalation solution at the end of this Patient Information leaflet.

Use arformoterol tartrate inhalation solution exactly as prescribed. **Do not use arformoterol tartrate inhalation solution more often than prescribed.**

One unit-dose ampule of arformoterol tartrate inhalation solution is 1 dose. The usual dose of arformoterol tartrate inhalation solution is 1 unit-dose ampule, 2 times a day (morning and evening) breathed in through your nebulizer machine. The 2 doses should be taken about 12 hours apart. **Do not use more than 2 unit-dose ampules of arformoterol tartrate inhalation solution a day.**

Do not swallow or inject arformoterol tartrate inhalation solution.

Arformoterol tartrate inhalation solution is for use with a standard jet nebulizer machine connected to an air compressor. Read the complete instructions for use at the end of this Patient Information leaflet before starting arformoterol tartrate inhalation solution.

Do not mix other medicines with arformoterol tartrate inhalation solution in your nebulizer machine.

While you are using arformoterol tartrate inhalation solution 2 times each day:

- Do not use other medicines that contain a long-acting beta₂-agonist (LABA) for any reason.
- Do not use your short-acting beta₂-agonist medicine on a regular basis (four times a day).

Arformoterol tartrate inhalation solution does not relieve sudden symptoms of COPD. Always have a rescue inhaler medicine with you to treat sudden symptoms. If you do not have a rescue inhaler medicine, call your healthcare provider to have one prescribed for you.

Do not stop using arformoterol tartrate inhalation solution or other medicines to control or treat your COPD unless told to do so by your healthcare provider because your symptoms might get worse. Your healthcare provider will change your medicines as needed.

Call your healthcare provider or get emergency medical care right away if your breathing problems worsen with arformoterol tartrate inhalation solution, you need to use your rescue medicine more often than usual, or your rescue inhaler medicine does not work as well for you at relieving symptoms.

What are the possible side effects of arformoterol tartrate inhalation solution?

Arformoterol tartrate inhalation solution can cause serious side effects, including:

people with asthma who take long-acting beta₂-adrenergic agonist (LABA) medicines, such as arformoterol (the medicine in arformoterol tartrate inhalation solution), without also using a medicine called an inhaled corticosteroid have an increased risk of serious problems from asthma, including being hospitalized, needing a tube placed in their airway to help them breath, or death.

Call your healthcare provider if breathing problems worsen over time while using arformoterol tartrate inhalation solution. You may need a different treatment.

Get emergency medical care if:

- your breathing problems worsen quickly.
- you use a rescue inhaler medicine, but it does not relieve your breathing problems.

COPD symptoms that get worse over time. If your COPD symptoms worsen over time, do not increase your dose of **arformoterol tartrate inhalation solution**, instead call your healthcare provider.

using too much of a LABA medicine may cause:

- chest pain
- increased blood pressure
- fast and irregular heartbeat
- headache
- tremor
- nervousness

sudden shortness of breath immediately after use of arformoterol tartrate inhalation solution. Sudden shortness of breath may be life threatening. If you have sudden breathing problems immediately after inhaling your medicine, stop taking arformoterol tartrate inhalation solution and call your healthcare provider or go to the nearest hospital emergency room right away.

effects on the heart which may include:

- increased blood pressure
- chest pain
- a fast or irregular heartbeat,
- awareness of a heartbeat

serious allergic reactions including rash, hives, swelling of the face, mouth, and tongue, and breathing problems. Call your healthcare provider or get emergency medical care if you get any symptoms of a serious allergic reaction.

Changes in laboratory levels, including high levels of blood sugar (hyperglycemia) and low levels of potassium (hypokalemia).

Common side effects of arformoterol tartrate inhalation solution include:

- pain
- sinus congestion
- rash
- chest congestion or bronchitis
- chest or back pain
- leg cramps
- flu-like symptoms
- diarrhea
- trouble breathing
- swelling in your legs

Tell your healthcare provider if you get any side effect that bothers you or that does not go away.

These are not all the possible side effects of arformoterol tartrate inhalation solution. **Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

How should I store arformoterol tartrate inhalation solution?

Store arformoterol tartrate inhalation solution in a refrigerator between 36° to 46°F (2° to 8°C) in the protective foil pouch. Protect from light and excessive heat. **Do not open a sealed pouch until you are ready to use a dose of arformoterol tartrate inhalation solution. After opening the pouch, unused unit-dose ampules should be returned to, and stored in, the pouch. An opened unit-dose ampule should be used right away.**

Arformoterol tartrate inhalation solution may also be stored at room temperature between 68° to 77°F (20° to 25°C) for up to 6 weeks (42 days). If stored at room temperature, discard arformoterol tartrate inhalation solution if it is not used after 6 weeks or if past the expiration date, whichever is sooner. Space is provided on the packaging to record room temperature storage times.

Do not use arformoterol tartrate inhalation solution after the expiration date provided on the foil pouch and unit-dose ampule.

Arformoterol tartrate inhalation solution should be colorless. Throw away (discard) arformoterol tartrate inhalation solution if it is not colorless.

Keep arformoterol tartrate inhalation solution and all medicines out of the reach of children.

General information about the safe and effective use of arformoterol tartrate inhalation solution.

Medicines are sometimes prescribed for purposes not mentioned in this Patient Information leaflet. Do not use arformoterol tartrate inhalation solution for a condition for which it was not prescribed. Do not give arformoterol tartrate inhalation solution to other people, even if they have the same symptoms that you may have. It may harm them.

You can ask your pharmacist or healthcare provider for information about arformoterol tartrate inhalation solution that was written for health professionals.

What are the ingredients in arformoterol tartrate inhalation solution?

Active ingredient: arformoterol tartrate

Inactive ingredients: citric acid, sodium chloride, and sodium citrate

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Manufactured In England By: **Norton Healthcare Limited T/A IVAX Pharmaceuticals UK**, Runcorn, Cheshire WA7 3FA England

Manufactured For: **Teva Pharmaceuticals USA, Inc.**, Parsippany, NJ 07054
For more information call Teva Pharmaceuticals USA, Inc. at 1-888-838-2872.

This Patient Information has been approved by the Food and Drug Administration. Iss. 5/2021

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- Carefully twist open the top of the unit-dose ampule and use it right away (**Figure 1**).

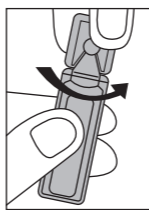


Figure 1

- Squeeze all of the medicine from the unit-dose ampule into the nebulizer medicine cup (reservoir) (**Figure 2**).



Figure 2

- Connect the nebulizer reservoir to the mouthpiece (**Figure 3**) or face mask (**Figure 4**).

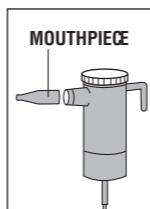


Figure 3



Figure 4

- Connect the nebulizer to the compressor (**Figure 5**).

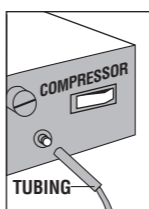


Figure 5

- Sit in a comfortable, upright position. Place the mouthpiece in your mouth (**Figure 6**) (or put on the face mask) and turn on the compressor.

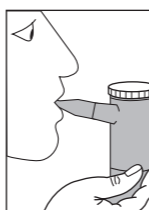


Figure 6

- Breathe as calmly, deeply, and evenly as possible until no more mist is formed in the nebulizer reservoir. It takes about 5 to 10 minutes for each treatment.
- Clean the nebulizer (see manufacturer's instructions).

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