

opened vial should be used right away.

If the recommended maintenance treatment regimen fails to provide the usual response, medical advice should be sought immediately, as this is often a sign of destabilization of COPD. Under these circumstances, the therapeutic regimen should be re-evaluated and additional therapeutic options should be considered.

No dose adjustment is required for patients with renal or hepatic impairment. However, since the clearance of BROVANA is prolonged in patients with hepatic impairment, they should be monitored closely.

The drug compatibility (physical and chemical), efficacy, and safety of BROVANA when mixed with other drugs in a nebulizer have not been established.

The safety and efficacy of BROVANA have been established in clinical trials when administered using the PARI LC PLUS<sup>®</sup> nebulizers and PARI DURA-NEB<sup>®</sup> 3000 compressors. The safety and efficacy of BROVANA when administered using other nebulizer systems has not been established.

## HOW SUPPLIED

BROVANA (arformoterol tartrate) Inhalation Solution is supplied in a single strength (15 mcg of arformoterol, equivalent to 22 mcg of arformoterol tartrate) as 2 mL of a sterile solution in unit-dose, low-density polyethylene (LDPE) vials overwrapped in foil. BROVANA is available in a shelf-carton containing 30 or 60 vials.

NDC 63402-911-30: carton of 30 unit-dose individually pouched vials.

NDC 63402-911-64: carton of 60 unit-dose vials (15x4 vial pouches).

CAUTION: Federal law (U.S.) prohibits dispensing without prescription.

## Storage

Store BROVANA in the protective foil pouch under refrigeration at 36°-46°F (2°-8°C). Protect from light and excessive heat. After opening the pouch, unused vials should be returned to, and stored in, the pouch. An opened vial should be used right away. Discard any vial if the solution is not colorless. Unopened foil pouches of BROVANA can also be stored at room temperature 68°-77°F, (20°-25°C) for up to 6 weeks. If stored at room temperature, discard if not used after 6 weeks or if past the expiration date, whichever is sooner.

## Sepracor

Manufactured for:

**Sepracor Inc.**

Marlborough, MA 01752 USA

For customer service, call 1-888-394-7377.

To report adverse events, call 1-877-737-7226.

For medical information, call 1-800-739-0565.

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## MEDICATION GUIDE

**BROVANA** [Brō vā `-nah]

## **(arformoterol tartrate) Inhalation Solution**

### **IMPORTANT USE INFORMATION**

1. **BROVANA 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 Medication Guide before starting BROVANA.**
2. **Do not swallow or inject BROVANA. BROVANA is for inhalation use only.**

Read the Medication Guide that comes with BROVANA before you start using it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment.

### **What is the most important information I should know about BROVANA?**

BROVANA is a medicine called a long-acting beta<sub>2</sub>-agonist or LABA. BROVANA is used to treat chronic obstructive pulmonary disease (COPD).

- **In patients with asthma, LABA medicines such as BROVANA may increase the chance of asthma-related death from asthma problems.**
- **It is not known if LABA medicines, such as BROVANA, increase the chance of death in patients with chronic obstructive pulmonary disease (COPD).**
- **BROVANA does not relieve sudden symptoms of COPD.** Always have a short-acting beta<sub>2</sub>-agonist medicine with you to treat sudden symptoms. If you do not have an inhaled short-acting bronchodilator, call your healthcare provider to have one prescribed for you.
- **Get emergency medical care if:**
  - **breathing problems worsen quickly**
  - **you use your short-acting beta<sub>2</sub>-agonist medicine, but it does not relieve your breathing problems**
- **Do not stop using BROVANA unless told to do so by your healthcare provider because your symptoms might get worse.**
- **BROVANA should not be used in children. BROVANA has not been studied in children.**

### **What is BROVANA?**

**BROVANA is used long term, twice a day (morning and evening), in controlling symptoms of chronic obstructive pulmonary disease (COPD) in adults with COPD.**

LABA medicines such as BROVANA help the muscles around the airways in your lungs stay relaxed to prevent symptoms, such as wheezing, cough, chest tightness, and shortness of breath.

### **What should I tell my healthcare provider before using BROVANA?**

**Tell your healthcare provider about all of your health conditions, including if you:**

- **have heart problems**
- **have high blood pressure**
- **have seizures**
- **have thyroid problems**
- **have diabetes**
- **have liver problems**

- dry mouth
- muscle cramps
- nausea, vomiting
- dizziness
- tiredness
- low or high blood potassium
- high blood sugar
- high blood acid
- trouble sleeping

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

These are not all the side effects with BROVANA. Ask your healthcare provider or pharmacist for more information.

### How should I store BROVANA?

- Store BROVANA 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 BROVANA. After opening the pouch, unused vials should be returned to, and stored in, the pouch. An opened vial should be used right away.** BROVANA may be used directly from the refrigerator.
- BROVANA may also be stored at room temperature between 68°F to 77°F (20°C to 25°C) for up to 6 weeks (42 days). If stored at room temperature, discard BROVANA 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 BROVANA after the expiration date provided on the foil pouch and vial.
- BROVANA should be colorless. Discard BROVANA if it is not colorless.
- **Keep BROVANA and all medicines out of the reach of children.**

### General Information about BROVANA

Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not use BROVANA for a condition for which it was not prescribed. Do not give BROVANA to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about BROVANA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about BROVANA that was written for healthcare professionals.

- For customer service, call 1-888-394-7377.
- To report side effects, call 1-877-737-7226.
- For medical information, call 1-800-739-0565.

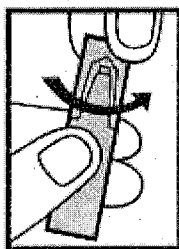
### Instructions for Using BROVANA (arformoterol tartrate) Inhalation Solution

**BROVANA 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 BROVANA or other medicines.**

**Do not mix BROVANA with other medicines in your nebulizer machine.**

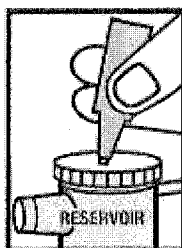
BROVANA comes sealed in a foil pouch. Do not open a sealed pouch until you are ready to use a dose of BROVANA. After opening the pouch, unused vials should be returned to, and stored in, the pouch. An opened vial should be used right away.

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



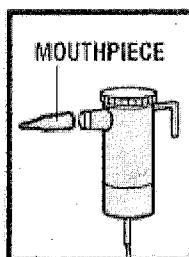
**Figure 1**

3. Squeeze all of the medicine from the vial 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**).

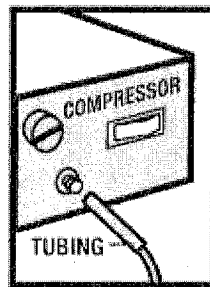


Figure 5

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.

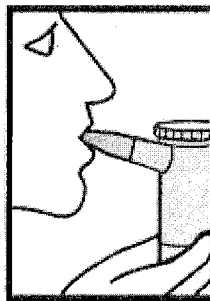


Figure 6

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).

Rx Only

This Medication Guide has been approved by the Food and Drug Administration.

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