

1 **MEDICATION GUIDE**
2 **BROVANA [Brō vǎ -nah]**
3 **(arformoterol tartrate) Inhalation Solution**
4

5 BROVANA is only for use with a nebulizer.
6

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

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

13 **BROVANA can cause serious side effects, including:**

- 14 • **People with asthma, who take long-acting beta₂ adrenergic**
15 **agonist (LABA) medicines, such as BROVANA, have an increased**
16 **risk of death from asthma problems.**
- 17 • It is not known if LABA medicines, such as BROVANA, increase the risk of
18 death in people with chronic obstructive pulmonary disease (COPD).
- 19 • **Get emergency medical care if:**
 - 20 • **breathing problems worsen quickly**
 - 21 • **you use your rescue inhaler medicine, but it does not relieve**
22 **your breathing problems**

23 **What is BROVANA?**

24 BROVANA is used long term, 2 times each day (morning and evening), in
25 controlling symptoms of chronic obstructive pulmonary disease (COPD) in
26 adults with COPD.
27

28 BROVANA is only for use with a nebulizer.

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

32 BROVANA should not be used in children. **It is not known if BROVANA is**
33 **safe and effective in children.**

34 **It is not known if BROVANA is safe and effective in people with**
35 **asthma.**

36

37 **Who should not use BROVANA?**

38 **Do not use BROVANA if you:**

- 39 • have had a serious allergic reaction to arformoterol, formoterol, or any
40 of the ingredients in BROVANA. Ask your healthcare provider if you are
41 not sure. See the end of this Medication Guide for a complete list of
42 ingredients in BROVANA.
- 43 • have asthma without using a long-term asthma controller medicine.

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

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

- 47 • have heart problems
- 48 • have high blood pressure
- 49 • have seizures
- 50 • have thyroid problems
- 51 • have diabetes
- 52 • have liver problems
- 53 • are pregnant or planning to become pregnant. It is not known if
54 BROVANA can harm your unborn baby.
- 55 • are breastfeeding. It is not known if BROVANA passes into your milk
56 and if it can harm your baby.

57 **Tell your healthcare provider about all the medicines you take**
58 including prescription and non-prescription medicines, vitamins and herbal
59 supplements. BROVANA and certain other medicines may interact with each
60 other. This may cause serious side effects.

61 Know the medicines you take. Keep a list of them to show your healthcare
62 provider and pharmacist each time you get a new medicine.

63 **How should I use BROVANA?**

64 **Read the step-by-step instructions for using BROVANA at the end of**
65 **this Medication Guide.**

- 66 • Use BROVANA exactly as prescribed. One ready-to-use vial of BROVANA
67 is one dose. The usual dose of BROVANA is 1 ready-to-use vial, twice a
68 day (morning and evening) breathed in through your nebulizer machine.
69 The 2 doses should be about 12 hours apart. **Do not use more than 2**
70 **ready-to-use vials of BROVANA a day.**
- 71 • Do not swallow or inject BROVANA.

- 72 • BROVANA is for use with a standard jet nebulizer machine connected to
73 an air compressor. Read the complete instructions for use at the end of
74 this Medication Guide before starting BROVANA.
- 75 • Do not mix other medicines with BROVANA in your nebulizer machine.
- 76 • If you miss a dose of BROVANA. Just skip that dose. Take your next
77 dose at your usual time. Do not take 2 doses at one time.
- 78 • While you are using BROVANA 2 times each day:
- 79 • **do not use** other medicines that contain a long-acting beta₂-agonist
80 (LABA) for any reason.
- 81 • **do not use** your short-acting beta₂-agonist medicine on a regular
82 basis (four times a day).
- 83 • **BROVANA does not relieve sudden symptoms of COPD.** Always have
84 a rescue inhaler medicine with you to treat sudden symptoms. If you do
85 not have a rescue inhaler medicine, call your healthcare provider to have
86 one prescribed for you.
- 87 • Do not stop using BROVANA or other medicines to control or treat your
88 COPD unless told to do so by your healthcare provider because your
89 symptoms might get worse. Your healthcare provider will change your
90 medicines as needed.
- 91 • **Do not use BROVANA:**
- 92 ○ **more often than prescribed**
- 93 ○ **more medicine than prescribed for you**
- 94 ○ **with other LABA medicines**
- 95 **Call your healthcare provider or get emergency medical care right**
96 **away if:**
- 97 • your breathing problems worsen with BROVANA
- 98 • you need to use your rescue inhaler medicine more often than usual
- 99 • your rescue inhaler medicine does not work as well for you at relieving
100 symptoms

101 **What are the possible side effects with BROVANA?**

102 **BROVANA can cause serious side effects, including:**

- 103 • **See “What is the most important information I should know about**
104 **BROVANA?”**
- 105 • Sudden shortness of breath immediately after use of Brovana

- 106 • If your COPD symptoms worsen over time do not increase your dose of
107 Brovana, instead call your healthcare provider.
- 108 • Increased blood pressure
- 109 • Fast or irregular heartbeat
- 110 • **serious allergic reactions including rash, hives, swelling of the**
111 **face, mouth, and tongue, and breathing problems.** Call your
112 healthcare provider or get emergency medical care if you get any
113 symptoms of a serious allergic reaction.

114

115 **Common side effects of BROVANA include:**

- 116 • **chest or back pain**
- 117 • **diarrhea**
- 118 • **sinus congestion**
- 119 • **headache**
- 120 • **tremor**
- 121 • **nervousness**
- 122 • **leg cramps**
- 123 • **high blood potassium**
- 124 • **shortness of breath**
- 125 • **rash**
- 126 • **fever**
- 127 • **increased white blood cells**
- 128 • **vomiting**
- 129 • **tiredness**
- 130 • **leg swelling**
- 131 • **chest congestion or bronchitis**

132

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

135 These are not all the side effects with BROVANA. Ask your healthcare
136 provider or pharmacist for more information. Call your doctor for medical
137 advice about side effects. You may report side effects to FDA at 1-800-FDA-
138 1088.

139 **How should I store BROVANA?**

- 140 • Store BROVANA in a refrigerator between 36° to 46°F (2° to 8°C) in the
141 protective foil pouch. Protect from light and excessive heat. **Do not**
142 **open a sealed pouch until you are ready to use a dose of**
143 **BROVANA. After opening the pouch, unused ready-to-use vials**
144 **should be returned to, and stored in, the pouch. An opened ready-**
145 **to-use vial should be used right away.** BROVANA may be used
146 directly from the refrigerator.
- 147 • BROVANA may also be stored at room temperature between 68°F to 77°F
148 (20°C to 25°C) for up to 6 weeks (42 days). If stored at room
149 temperature, discard BROVANA if it is not used after 6 weeks or if past
150 the expiration date, whichever is sooner. Space is provided on the
151 packaging to record room temperature storage times.
- 152 • Do not use BROVANA after the expiration date provided on the foil pouch
153 and ready-to-use vial.
- 154 • BROVANA should be colorless. Discard BROVANA if it is not colorless.
- 155 • **Keep BROVANA and all medicines out of the reach of children.**

156 **General Information about BROVANA**

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

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

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

168 **Instructions for Using BROVANA (arformoterol tartrate) Inhalation**
169 **Solution**

170

171 **BROVANA is used only in a standard jet nebulizer machine connected**
172 **to an air compressor. Make sure you know how to use your nebulizer**
173 **machine before you use it to breathe-in BROVANA or other**
174 **medicines.**

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

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

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

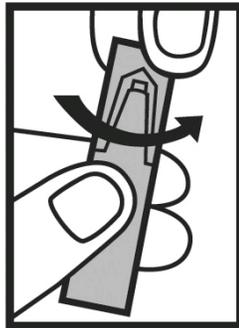


Figure 1

185

- 186 3. Squeeze all of the medicine from the ready-to-use vial into the
187 nebulizer medicine cup (reservoir) (**Figure 2**).



Figure 2

- 188
189 4. Connect the nebulizer reservoir to the mouthpiece (**Figure 3**) or face
190 mask (**Figure 4**).



Figure 3



Figure 4

191

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

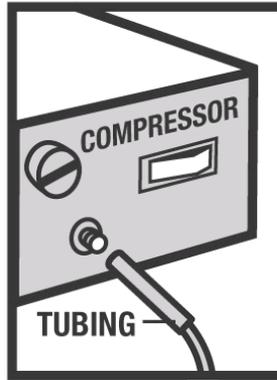


Figure 5

193

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

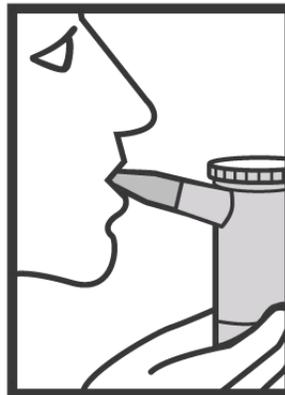


Figure 6

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

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

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206 Rx Only

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



209

210 Manufactured for:

211 **Sepracor Inc.**

212 Marlborough, MA 01752 USA

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