

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

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

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

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

22 **What is BROVANA?**

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

26
27 BROVANA is only for use with a nebulizer.

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

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

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

35 **Who should not use BROVANA?**

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

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

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

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

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

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

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

59 **How should I use BROVANA?**

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

- 62 • Use BROVANA exactly as prescribed. One ready-to-use vial of BROVANA is one
63 dose. The usual dose of BROVANA is 1 ready-to-use vial, twice a day (morning and
64 evening) breathed in through your nebulizer machine. The 2 doses should be about
65 12 hours apart. **Do not use more than 2 ready-to-use vials of BROVANA a day.**
- 66 • Do not swallow or inject BROVANA.

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

- 100 • Fast or irregular heartbeat
- 101 • **serious allergic reactions including rash, hives, swelling of the face, mouth, and**
- 102 **tongue, and breathing problems.** Call your healthcare provider or get emergency
- 103 medical care if you get any symptoms of a serious allergic reaction.

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

- 105 • **chest or back pain**
- 106 • **diarrhea**
- 107 • **sinus congestion**
- 108 • **headache**
- 109 • **tremor**
- 110 • **nervousness**
- 111 • **leg cramps**
- 112 • **high blood potassium**
- 113 • **shortness of breath**
- 114 • **rash**
- 115 • **fever**
- 116 • **increased white blood cells**
- 117 • **vomiting**
- 118 • **tiredness**
- 119 • **leg swelling**
- 120 • **chest congestion or bronchitis**

121 Tell your healthcare provider if you get any side effect that bothers you or that does not

122 go away.

123 These are not all the side effects with BROVANA. Ask your healthcare provider or

124 pharmacist for more information. Call your doctor for medical advice about side effects.

125 You may report side effects to FDA at 1-800-FDA-1088.

126 **How should I store BROVANA?**

- 127 • Store BROVANA in a refrigerator between 36° to 46°F (2° to 8°C) in the protective
- 128 foil pouch. Protect from light and excessive heat. **Do not open a sealed pouch until**
- 129 **you are ready to use a dose of BROVANA. After opening the pouch, unused**
- 130 **ready-to-use vials should be returned to, and stored in, the pouch. An opened**
- 131 **ready-to-use vial should be used right away.** BROVANA may be used directly
- 132 from the refrigerator.

- 133 • BROVANA may also be stored at room temperature between 68°F to 77°F (20°C to
134 25°C) for up to 6 weeks (42 days). If stored at room temperature, discard
135 BROVANA if it is not used after 6 weeks or if past the expiration date, whichever is
136 sooner. Space is provided on the packaging to record room temperature storage
137 times.
- 138 • Do not use BROVANA after the expiration date provided on the foil pouch and
139 ready-to-use vial.
- 140 • BROVANA should be colorless. Discard BROVANA if it is not colorless.
- 141 • **Keep BROVANA and all medicines out of the reach of children.**

142 **General Information about BROVANA**

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

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

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

153 **Instructions for Using BROVANA (arformoterol tartrate) Inhalation Solution**

154

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

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

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

163 1. Open the foil pouch by tearing on the rough edge along the seam of the pouch.
164 Remove a ready-to-use vial of BROVANA.

165 2. Carefully twist open the top of the ready-to-use vial and use it right away
166 **(Figure 1).**

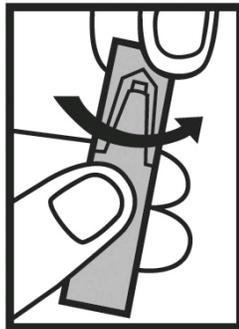


Figure 1

167

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



Figure 2

- 170
171 4. Connect the nebulizer reservoir to the mouthpiece (**Figure 3**) or face mask
172 (**Figure 4**).



Figure 3



Figure 4

173

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

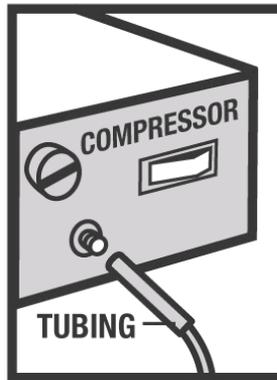


Figure 5

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

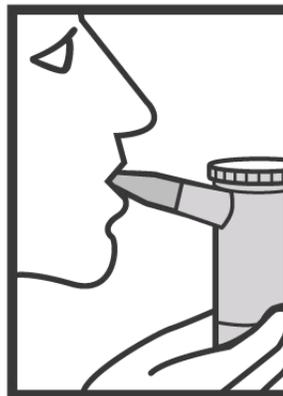


Figure 6

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

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186 Rx Only

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

188  **SUNOVION**
189 Manufactured for:
190 **Sunovion Pharmaceuticals Inc.**
191 Marlborough, MA 01752 USA
192

193 BROVANA is a registered trademark of Sunovion Pharmaceuticals Inc.

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