

1 **MEDICATION GUIDE**

2 **ADVAIR[®] HFA [*ad' vair*] 45/21 Inhalation Aerosol**
3 **(fluticasone propionate 45 mcg and salmeterol 21 mcg)**

4 **ADVAIR[®] HFA 115/21 Inhalation Aerosol**
5 **(fluticasone propionate 115 mcg and salmeterol 21 mcg)**

6 **ADVAIR[®] HFA 230/21 Inhalation Aerosol**
7 **(fluticasone propionate 230 mcg and salmeterol 21 mcg)**

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

13
14 **What is the most important information I should know about ADVAIR HFA?**

15 **ADVAIR HFA can cause serious side effects, including:**

- 16 1. **People with asthma who take long-acting beta₂-adrenergic agonist (LABA) medicines,**
17 **such as salmeterol (one of the medicines in ADVAIR HFA), have an increased risk of**
18 **death from asthma problems.** It is not known whether fluticasone propionate, the other
19 medicine in ADVAIR HFA, reduces the risk of death from asthma problems seen with
20 salmeterol.
- 21 • **Call your healthcare provider if breathing problems worsen over time while using**
22 **ADVAIR HFA.** You may need different treatment.
 - 23 • **Get emergency medical care if:**
 - 24 • breathing problems worsen quickly and
 - 25 • you use your rescue inhaler medicine, but it does not relieve your breathing problems.
- 26 2. ADVAIR HFA should be used only if your healthcare provider decides that your asthma is
27 not well controlled with a long-term asthma control medicine, such as inhaled
28 corticosteroids.
- 29 3. When your asthma is well controlled, your healthcare provider may tell you to stop taking
30 ADVAIR HFA. Your healthcare provider will decide if you can stop ADVAIR HFA without
31 loss of asthma control. Your healthcare provider may prescribe a different long-term asthma
32 control medicine for you, such as an inhaled corticosteroid.
- 33 4. Children and adolescents who take LABA medicines may have an increased risk of being
34 hospitalized for asthma problems.

35
36 **What is ADVAIR HFA?**

- 37 • ADVAIR HFA combines an inhaled corticosteroid medicine, fluticasone propionate (the
38 same medicine found in FLOVENT[®]), and a LABA medicine, salmeterol (the same medicine
39 found in SEREVENT[®]).
- 40 • Inhaled corticosteroids help to decrease inflammation in the lungs. Inflammation in the
41 lungs can lead to asthma symptoms.
- 42 • LABA medicines are used in people with asthma and chronic obstructive pulmonary
43 disease (COPD). LABA medicines help the muscles around the airways in your lungs
44 stay relaxed to prevent symptoms, such as wheezing and shortness of breath. These
45 symptoms can happen when the muscles around the airways tighten. This makes it hard
46 to breathe. In severe cases, wheezing can stop your breathing and cause death if not
47 treated right away.
- 48 • ADVAIR HFA is used to control symptoms of asthma and to prevent symptoms such as
49 wheezing in adults and children aged 12 years and older.
- 50 • ADVAIR HFA contains salmeterol (the same medicine found in SEREVENT). LABA
51 medicines, such as salmeterol, increase the risk of death from asthma problems.

52 ADVAIR HFA is not for adults and children with asthma who are well controlled with an asthma
53 control medicine, such as a low to medium dose of an inhaled corticosteroid medicine.
54

55 **Who should not use ADVAIR HFA?**

56 Do not use ADVAIR HFA:

- 57 • to treat sudden, severe symptoms of asthma and
58 • if you are allergic to any of the ingredients in ADVAIR HFA. See the end of this
59 Medication Guide for a list of ingredients in ADVAIR HFA.
60

61 **What should I tell my healthcare provider before using ADVAIR HFA?**

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

- 63 • **have heart problems**
64 • **have high blood pressure**
65 • **have seizures**
66 • **have thyroid problems**
67 • **have diabetes**
68 • **have liver problems**
69 • **have osteoporosis**
70 • **have an immune system problem**
71 • **are pregnant or planning to become pregnant.** It is not known if ADVAIR HFA may
72 harm your unborn baby.

73 • **are breastfeeding.** It is not known if ADVAIR HFA passes into your milk and if it can
74 harm your baby.

75 • **are allergic to ADVAIR HFA or any other medicines**

76 • **are exposed to chickenpox or measles**

77 Tell your healthcare provider about all the medicines you take including prescription and
78 non-prescription medicines, vitamins, and herbal supplements. ADVAIR HFA and certain other
79 medicines may interact with each other. This may cause serious side effects. Especially, tell your
80 healthcare provider if you take ritonavir. The anti-HIV medicines NORVIR[®] (ritonavir capsules)
81 Soft Gelatin, NORVIR (ritonavir oral solution), and KALETRA[®] (lopinavir/ritonavir) Tablets
82 contain ritonavir.

83 Know the medicines you take. Keep a list and show it to your healthcare provider and pharmacist
84 each time you get a new medicine.

85

86 **How do I use ADVAIR HFA?**

87 **See the step-by-step instructions for using ADVAIR HFA at the end of this Medication**
88 **Guide.** Do not use ADVAIR HFA unless your healthcare provider has taught you and you
89 understand everything. Ask your healthcare provider or pharmacist if you have any questions.

90 • Use ADVAIR HFA exactly as prescribed. **Do not use ADVAIR HFA more often**
91 **than prescribed.** ADVAIR HFA comes in 3 strengths. Your healthcare provider has
92 prescribed the one that is best for your condition.

93 • The usual dosage of ADVAIR HFA is 2 inhalations 2 times each day (morning and
94 evening). The 2 doses should be about 12 hours apart. Rinse your mouth with water after
95 using ADVAIR HFA.

96 • If you miss a dose of ADVAIR HFA, just skip that dose. Take your next dose at your
97 usual time. Do not take 2 doses at one time.

98 • **While you are using ADVAIR HFA 2 times each day, do not use other medicines**
99 **that contain a LABA for any reason.** Ask your healthcare provider or pharmacist if any of
100 your other medicines are LABA medicines.

101 • Do not stop using ADVAIR HFA or other asthma medicines unless told to do so by
102 your healthcare provider because your symptoms might get worse. Your healthcare provider
103 will change your medicines as needed.

104 • ADVAIR HFA does not relieve sudden symptoms. Always have a rescue inhaler
105 medicine with you to treat sudden symptoms. If you do not have an inhaled, short-acting
106 bronchodilator, call your healthcare provider to have one prescribed for you.

107 • Call your healthcare provider or get medical care right away if:

108 • your breathing problems worsen with ADVAIR HFA

- 109 • you need to use your rescue inhaler medicine more often than usual
- 110 • your rescue inhaler medicine does not work as well for you at relieving symptoms
- 111 • you need to use 4 or more inhalations of your rescue inhaler medicine for 2 or more
- 112 days in a row
- 113 • you use 1 whole canister of your rescue inhaler medicine in 8 weeks' time
- 114 • your peak flow meter results decrease. Your healthcare provider will tell you the
- 115 numbers that are right for you.
- 116 • you have asthma and your symptoms do not improve after using ADVAIR HFA
- 117 regularly for 1 week
- 118

119 **What are the possible side effects with ADVAIR HFA?**

120 **ADVAIR HFA can cause serious side effects, including:**

- 121 • **See “What is the most important information I should know about ADVAIR HFA?”**
- 122 • **serious allergic reactions.** Call your healthcare provider or get emergency medical
- 123 care if you get any of the following symptoms of a serious allergic reaction:
 - 124 • rash
 - 125 • hives
 - 126 • swelling of the face, mouth, and tongue
 - 127 • breathing problems
- 128 • **sudden breathing problems immediately after inhaling your medicine**
- 129 • **effects on heart**
 - 130 • increased blood pressure
 - 131 • a fast and irregular heartbeat
 - 132 • chest pain
- 133 • **effects on nervous system**
 - 134 • tremor
 - 135 • nervousness
- 136 • **reduced adrenal function (may result in loss of energy)**
- 137 • **changes in blood (sugar, potassium, certain types of white blood cells)**
- 138 • **weakened immune system and a higher chance of infections**
- 139 • **lower bone mineral density.** This may be a problem for people who already have a
- 140 higher chance of low bone density (osteoporosis).
- 141 • **eye problems including glaucoma and cataracts.** You should have regular eye exams
- 142 while using ADVAIR HFA.
- 143 • **slowed growth in children.** A child's growth should be checked often.

- 144 • **throat tightness**
- 145 • **pneumonia.** ADVAIR HFA contains the same medicine found in ADVAIR DISKUS[®].
146 ADVAIR DISKUS is used to treat people with asthma and people with chronic obstructive
147 pulmonary disease (COPD). People with COPD have a higher chance of getting pneumonia.
148 ADVAIR DISKUS may increase the chance of getting pneumonia. ADVAIR HFA has not
149 been studied in people with COPD. Call your healthcare provider if you notice any of the
150 following symptoms:
- 151 • increase in mucus (sputum) production
 - 152 • change in mucus color
 - 153 • fever
 - 154 • chills
 - 155 • increased cough
 - 156 • increased breathing problems

157 **Common side effects of ADVAIR HFA include:**

- 158 • upper respiratory tract infection
- 159 • headache
- 160 • throat irritation
- 161 • musculoskeletal pain
- 162 • nausea and vomiting

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

164 These are not all the side effects with ADVAIR HFA. Ask your healthcare provider or
165 pharmacist for more information.

166 Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-
167 800-FDA-1088.

168

169 **How do I store ADVAIR HFA?**

- 170 • Store at room temperature with the mouthpiece down.
- 171 • **Contents Under Pressure:** Do not puncture. Do not use or store near heat or open flame.
172 Exposure to temperatures above 120°F may cause bursting.
- 173 • Do not throw into fire or an incinerator.
- 174 • Keep ADVAIR HFA and all medicines out of the reach of children.

175

176 **General Information about ADVAIR HFA**

177 Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not
178 use ADVAIR HFA for a condition for which it was not prescribed. Do not give your ADVAIR
179 HFA to other people, even if they have the same condition that you have. It may harm them.

180 This Medication Guide summarizes the most important information about ADVAIR HFA. If you
181 would like more information, talk with your healthcare provider or pharmacist. You can ask your
182 healthcare provider or pharmacist for information about ADVAIR HFA that was written for
183 healthcare professionals. You can also contact the company that makes ADVAIR HFA (toll free)
184 at 1-888-825-5249 or at www.advail.com.

185

186 **What are the ingredients in ADVAIR HFA?**

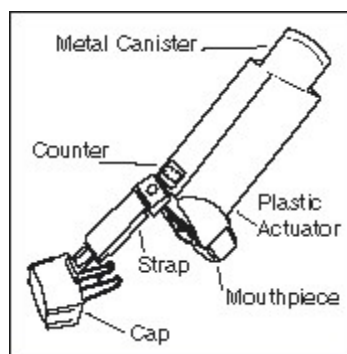
187 Active ingredients: fluticasone propionate, salmeterol xinafoate

188 Inactive ingredient: propellant HFA-134a

189

190 **How to use your ADVAIR HFA**

191 **The parts of your ADVAIR HFA:**



192

193

Figure 1

194 There are 2 main parts to your ADVAIR HFA inhaler—
195 the metal canister that holds the medicine and the purple
196 plastic actuator that sprays the medicine from the canister
197 (see Figure 1).

198 The inhaler also has a cap that covers the mouthpiece of
199 the actuator. The strap on the cap will stay attached to the
200 actuator.

201 **Do not use the actuator with a canister of medicine**
202 **from any other inhaler. Do not use an ADVAIR HFA**
203 **canister with an actuator from any other inhaler.**

204 The canister has a counter to show how many sprays of medicine you have left. The number
205 shows through a window in the back of the actuator.

206 The counter starts at 124, or at 064 if you have a sample or institutional canister. The number
207 will count down by 1 each time you spray the inhaler. The counter will stop counting at 000.

208 **Never try to change the numbers or take the counter off the metal canister.** The counter
209 cannot be reset, and it is permanently attached to the canister.

210 **Before using your ADVAIR HFA:**

211 Take the inhaler out of the foil pouch. Safely throw away the foil pouch and the drying packet
212 that comes inside the pouch. The counter should read 124, or 064 if you have a sample or
213 institutional canister.

214 The inhaler should be at room temperature before you use it.

215 Check each time to make sure the canister fits firmly in the plastic actuator. Also look into the
216 mouthpiece to make sure there are no foreign objects there, especially if the strap is no longer
217 attached to the actuator or if the cap is not being used to cover the mouthpiece.

218 **Priming your ADVAIR HFA:**

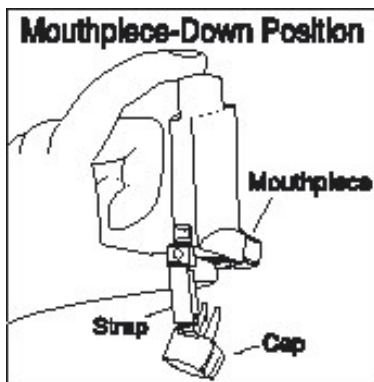
219 Before you use ADVAIR HFA for the first time, you must prime the inhaler so that you will
220 get the right amount of medicine when you use it. To prime the inhaler, take the cap off the

221 mouthpiece and shake the inhaler well for 5 seconds. Then spray it 1 time into the air away from
222 your face. Shake and spray the inhaler like this 3 more times to finish priming it. **Avoid**
223 **spraying in eyes.** The counter should now read 120, or 060 if you have a sample or institutional
224 canister.

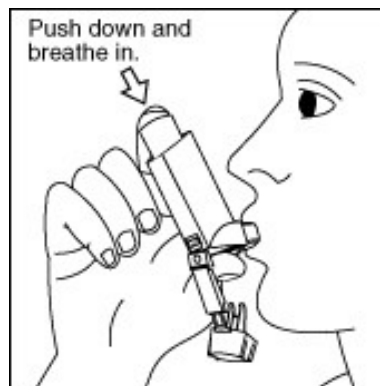
225 You must prime your inhaler again if you have not used it in more than 4 weeks or if you have
226 dropped it. Take the cap off the mouthpiece, shake the inhaler well for 5 seconds, and spray it
227 into the air away from your face. Shake and spray the inhaler like this 1 more time to finish
228 priming it.

229 **Instructions for taking a dose from your ADVAIR HFA:**

230 Read through the 7 steps below before using ADVAIR HFA. If you have any questions, ask
231 your doctor or pharmacist.



232
233 **Figure 2**



235
236 **Figure 3**

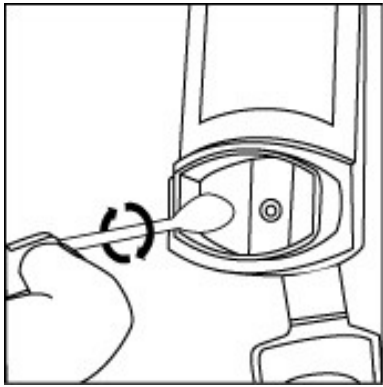
- 237 1. Take the cap off the mouthpiece of the actuator. **Shake the inhaler well** for 5 seconds before
238 each spray.
- 239 1. Hold the inhaler with the mouthpiece down (see Figure 2). **Breathe out through your mouth**
240 and push as much air from your lungs as you can. Put the mouthpiece in your mouth and close
241 your lips around it.
- 242 2. **Push the top of the canister all the way down while you breathe in deeply and slowly**
243 **through your mouth** (see Figure 3). Right after the spray comes out, take your finger off the
244 canister. After you have breathed in all the way, take the inhaler out of your mouth and close
245 your mouth.
- 246 3. **Hold your breath as long as you can**, up to 10 seconds, then breathe normally.
- 247 4. Wait about 30 seconds and **shake** the inhaler again for 5 seconds. Repeat steps 2 through 4.
- 248 5. After you finish taking this medicine, rinse your mouth with water. Spit out the water. Do not
249 swallow it.
- 250 6. Put the cap back on the mouthpiece after every time you use the inhaler, and make sure it
251 snaps firmly into place.

252 **When to replace your ADVAIR HFA:**

- 253 • **When the counter reads 020**, you should refill your prescription or ask your doctor if you
254 need another prescription for ADVAIR HFA.
- 255 • **Throw the inhaler away** when the counter reads 000. You should not keep using the inhaler
256 when the counter reads 000 because you will not receive the right amount of medicine.
- 257 • **Do not use the inhaler** after the expiration date, which is on the packaging it comes in.

258 **How to clean your ADVAIR HFA:**

259 Clean the inhaler at least once a week after your evening dose. It is important to keep the
260 canister and plastic actuator clean so the medicine will not build-up and block the spray.



261 **Figure 4**

- 263 1. Take the cap off the mouthpiece. The strap on the cap
264 will stay attached to the actuator. Do not take the canister
265 out of the plastic actuator.
- 266 7. Use a dry cotton swab to clean the small circular
267 opening where the medicine sprays out of the canister.
268 Carefully twist the swab in a circular motion to take off
269 any medicine (see Figure 4).
- 270 8. Wipe the inside of the mouthpiece with a clean tissue
271 dampened with water. Let the actuator air-dry overnight.
- 272 9. Put the cap back on the mouthpiece after the actuator has
273 dried.

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

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