

1 **Patient's Instructions for Use**

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3 **(illustration of 3 products)**

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5 **FLOVENT[®] HFA 44 mcg**
6 **(fluticasone propionate, 44 mcg)**
7 **Inhalation Aerosol**

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9 **FLOVENT[®] HFA 110 mcg**
10 **(fluticasone propionate, 110 mcg)**
11 **Inhalation Aerosol**

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13 **FLOVENT[®] HFA 220 mcg**
14 **(fluticasone propionate, 220 mcg)**
15 **Inhalation Aerosol**

16
17 **FOR ORAL INHALATION ONLY**

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19 Read this leaflet carefully before using your FLOVENT HFA Inhalation Aerosol and
20 each time you get a refill. There may be new information. Do not throw it away until you
21 have finished your medicine.

22 This leaflet does not contain all the information about your medicine. If you have any
23 questions or are not sure about something, you should ask your doctor or pharmacist.

24 This medicine has been prescribed for you by your doctor. DO NOT give this
25 medicine to anyone else.

26 **What Is FLOVENT HFA Inhalation Aerosol?**

27 FLOVENT HFA contains a medicine called fluticasone propionate, which is a
28 synthetic corticosteroid. Corticosteroids are natural substances found in the body that
29 help fight inflammation. Corticosteroids are used to treat asthma because they reduce
30 airway inflammation.

31 FLOVENT HFA is used to treat asthma in patients 4 years of age and older. When
32 inhaled regularly, FLOVENT HFA also helps to prevent symptoms of asthma.

33 The medicine is available in 3 different strengths, FLOVENT HFA 44 mcg,
34 FLOVENT HFA 110 mcg, or FLOVENT HFA 220 mcg Inhalation Aerosol, and your
35 doctor has prescribed the one most suitable for you.

Important Points to Remember About Using FLOVENT HFA Inhalation Aerosol

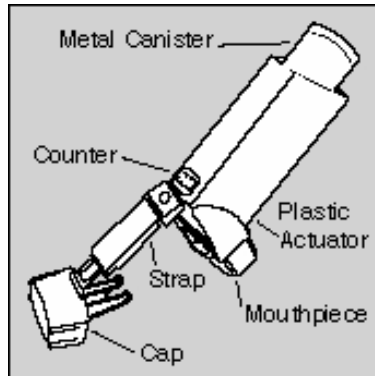
- 36
- 37 1. FLOVENT HFA is not a bronchodilator and should not be used to give you fast relief
38 from your breathing problems during an asthma attack. You should use a short-acting
39 bronchodilator, such as albuterol inhaler, during an acute asthma attack. You must
40 take FLOVENT HFA at regular times as recommended by your doctor, and not as an
41 emergency medicine.
- 42 2. **Tell your doctor before you start taking FLOVENT HFA if you are:**
- 43 • pregnant or planning to become pregnant.
 - 44 • breastfeeding a baby.
 - 45 • allergic to FLOVENT HFA, either of its ingredients, or any other orally inhaled
46 corticosteroids.
 - 47 • taking a medicine containing ritonavir (commonly used to treat HIV infection or
48 AIDS). The anti-HIV medicines NORVIR[®] (ritonavir capsules) Soft Gelatin,
49 NORVIR (ritonavir oral solution), and KALETRA[®] (lopinavir/ritonavir) Tablets
50 contain ritonavir.
 - 51 • taking other medicines, especially any other orally inhaled corticosteroid, over-the-
52 counter medicines, and herbal products.
- 53 There may be a time when FLOVENT HFA is not right for you, and your doctor
54 may wish to give you a different medicine. Make sure that your doctor knows what
55 other medicines you are taking.
- 56 3. It is important that you inhale each dose as your doctor has advised. The prescription
57 label provided by your pharmacist will usually tell you what dose to take and how
58 often. If it doesn't, or if you are not sure, ask your doctor or pharmacist. **DO NOT**
59 inhale more doses or use your FLOVENT HFA more often than your doctor advises.
- 60 4. It may take 1 to 2 weeks or longer for this medicine to work, and it is very important
61 that you use it regularly. **Do not stop taking FLOVENT HFA, even if you are**
62 **feeling better, unless your doctor tells you to.**
- 63 5. If you miss a dose, just take your next scheduled dose when it is due. **Do not double**
64 **the dose.**
- 65 6. Your doctor may prescribe additional medicine (such as bronchodilators) for
66 emergency relief if an acute asthma attack occurs. Contact your doctor if:
67 • an asthma attack does not respond to the additional medicine or
68 • you need more of the additional medicine than usual.
- 69 7. If you also use another medicine by inhalation, you should ask your doctor for
70 instructions on when to use it while you are also using FLOVENT HFA.

71

How to Use Your FLOVENT HFA Inhalation Aerosol

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The Parts of Your FLOVENT HFA Inhalation Aerosol:



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Figure 1

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The strap on the cap stays attached to the actuator when you take the cap off the mouthpiece of the actuator. You should keep the mouthpiece covered with the cap when not in use.

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Look inside the mouthpiece for foreign objects before each use, especially if the strap is no longer attached to the actuator or if the cap is not being used to cover the mouthpiece.

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The dark orange actuator that comes with FLOVENT HFA should not be used with any other product canisters. Actuators that come with other products should not be used with a FLOVENT HFA canister.

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The metal canister is fitted with a counter to show the number of sprays of medicine you have left. The number will show through a window in the back of the plastic actuator (see Figure 1). The counter starts at 124 (which includes the first 4 priming sprays) and counts down to 000. Each time you spray the inhaler, the number will count down by 1. The counter will stop counting at 000. **Never try to change the numbers or take the counter off the metal canister.** The counter cannot be reset and is permanently attached to the canister.

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Priming Your FLOVENT HFA Inhalation Aerosol:

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It is important to prime FLOVENT HFA as follows to make sure you get the right amount of medicine.

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Prime FLOVENT HFA before using it for the first time. Take your FLOVENT HFA out of the overwrap and safely throw away the overwrap and drying packet, which is also inside the overwrap. The counter should read 124.

92

93

To prime the inhaler, take the cap off the mouthpiece of the actuator (the strap on the cap will stay attached to the actuator). Shake the inhaler well for 5 seconds and spray it

99 into the air away from your face 4 times; shake it well before each spray. The counter
100 should read 120 after you have primed the inhaler the first time.

101 **Prime FLOVENT HFA when the inhaler has not been used for more than 7 days**
102 **or when it has been dropped.** To prime the inhaler, take the cap off the mouthpiece of
103 the actuator (the strap on the cap will stay attached to the actuator). Shake the inhaler
104 well for 5 seconds and spray it into the air away from your face 1 time. When you prime
105 the inhaler during regular use, the counter number will count down by 1 each time you
106 spray the inhaler.

107 **Using Your FLOVENT HFA Inhalation Aerosol:**

108 Follow the instructions below. If you have any questions, ask your doctor or
109 pharmacist.

110 **Children 4 years of age and older should use FLOVENT HFA under adult**
111 **supervision, as instructed by the child's doctor.**

112 The inhaler should be at room temperature before use.

113 **1. Take the cap off the mouthpiece of the actuator** (see Figure 2).

114 Look inside the mouthpiece for foreign objects, and take out any you see.

115 Make sure the canister is fully and firmly inserted into the actuator.

116 **Shake the inhaler well** for 5 seconds right before each use.

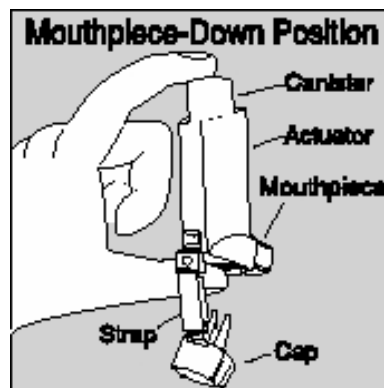


Figure 2

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120 **2. Breathe out fully through your mouth,** pushing as much air out of your lungs as you
121 can.

122 Put the mouthpiece all the way into your mouth. Hold the inhaler with the mouthpiece
123 down (see Figure 3). Close your lips around it.

124 **3. It is important to get the medicine in the spray into your lungs where it works. To do**
125 **this, you need to inhale the spray at the same time you take in a slow, deep breath.**

126 So, just after starting to take in a slow, deep breath through your mouth, press down
127 firmly on the top of the metal canister and keep breathing in through your mouth (see
128 Figure 3).

129 Take your finger off the canister after the spray comes out of the canister. Take the
130 mouthpiece out of your mouth when you have finished breathing in.

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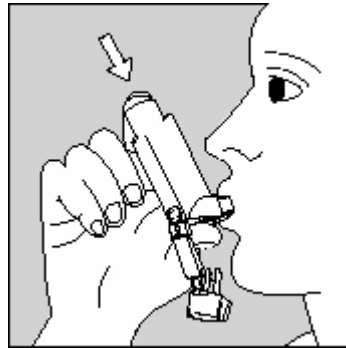


Figure 3

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135 **4. Hold your breath as long as you can**, up to 10 seconds. Then breathe normally.

136 **5. Wait about 30 seconds and shake** the inhaler well for 5 seconds. Repeat steps 2
137 through 4.

138 **6. Put the cap back on the mouthpiece after each time you use the inhaler.**

139 **7.** After you finish taking this medicine, rinse your mouth with water. Spit out the water.
140 Do not swallow it.

141 **8.** Never put the canister in water to find out how much medicine is left in the canister
142 (“float test”).

143

Cleaning Your FLOVENT HFA Inhalation Aerosol

144 Clean the inhaler at least once a week after your evening dose. Keeping the canister
145 and plastic actuator clean is important to prevent medicine buildup.

146 **Step 1.** Take the cap off the mouthpiece. The strap on the cap will stay attached to the
147 actuator. Do not take the canister out of the plastic actuator.

148 **Step 2.** Use a cotton swab dampened with water to clean the small circular opening where
149 the medicine sprays out of the canister. Gently twist the swab in a circular motion to
150 remove any medicine (see Figure 4). Repeat with a clean, water-dampened swab to take
151 off any medicine still at the opening.

152 Wipe the inside of the mouthpiece with a clean tissue dampened with water. Let the
153 actuator air-dry overnight.

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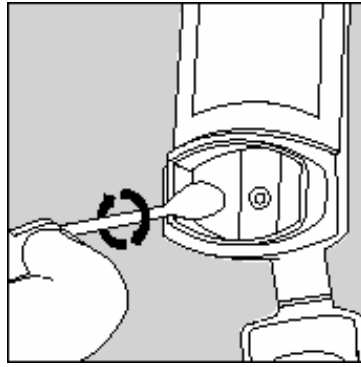


Figure 4

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158 Step 3. Put the cap back on the mouthpiece after the actuator has dried.

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Storing Your FLOVENT HFA Inhalation Aerosol

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Store at room temperature with the mouthpiece down. Keep out of reach of children.

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Contents Under Pressure: Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 120°F may cause bursting. Never throw into fire or incinerator.

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Throw away the inhaler when the counter reads 000. The right amount of medicine in each inhalation cannot be assured after the counter reads 000, even though the canister is not completely empty and will continue to operate. When the counter reads 020, you should refill your prescription or ask your doctor if you need a refill of your prescription. You should not take extra doses without talking to your doctor, and you should not stop using FLOVENT HFA without talking to your doctor.

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Do not use after the expiration date on the product label and box.

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Research Triangle Park, NC 27709

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