

842 **Information for the Patient**

843
844 **FLOVENT[®] [flō'vent] HFA 44 mcg**
845 **(fluticasone propionate 44 mcg)**
846 **Inhalation Aerosol**

847
848 **FLOVENT[®] HFA 110 mcg**
849 **(fluticasone propionate 110 mcg)**
850 **Inhalation Aerosol**

851
852 **FLOVENT[®] HFA 220 mcg**
853 **(fluticasone propionate 220 mcg)**
854 **Inhalation Aerosol**

855
856 **FOR ORAL INHALATION ONLY**

857
858 Read this leaflet carefully before you start to use FLOVENT HFA Inhalation Aerosol.

859 Keep this leaflet because it has important summary information about FLOVENT HFA. This
860 leaflet does not contain all the information about your medicine. If you have any questions or are
861 not sure about something, you should ask your doctor or pharmacist.

862 Read the new leaflet that comes with each refill of your prescription because there may be
863 new information.

864
865 **What is FLOVENT HFA?**

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

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

871 FLOVENT HFA comes in 3 strengths. Your doctor has prescribed the one that is best for your
872 condition.

873
874 **Who should not use FLOVENT HFA?**

875 Do not use FLOVENT HFA if you:

- 876 • are allergic to any of the ingredients in FLOVENT HFA or other inhaled corticosteroids. See
877 “What are the ingredients in FLOVENT HFA?” below.
- 878 • have an acute asthma attack or status asthmaticus. **FLOVENT HFA is not a bronchodilator**
879 **and should not be used to give you fast relief from your breathing problems during an**
880 **asthma attack.** Always use a short-acting bronchodilator (rescue medicine), such as

881 albuterol inhaler, during a sudden asthma attack. You must take FLOVENT HFA at regular
882 times as recommended by your doctor, and not as an emergency medicine.

883

884 **What should I tell my doctor before taking FLOVENT HFA?**

885 **Tell your doctor if you are:**

- 886 • pregnant or planning to become pregnant. It is not known if FLOVENT HFA will harm your
887 unborn baby.
- 888 • breastfeeding a baby. It is not known if FLOVENT HFA passes into your breast milk.
- 889 • exposed to chickenpox or measles.

890 Tell your doctor about all the medicines you take including prescription and non-prescription
891 medicines, vitamins, and herbal supplements. FLOVENT HFA may affect the way other
892 medicines work, and other medicines may affect how FLOVENT HFA works. Especially, tell
893 your doctor if you take:

- 894 • a medicine containing ritonavir (commonly used to treat HIV infection or AIDS). The
895 anti-HIV medicines NORVIR[®] (ritonavir capsules) Soft Gelatin, NORVIR (ritonavir oral
896 solution), and KALETRA[®] (lopinavir/ritonavir) Tablets contain ritonavir.
- 897 • any other corticosteroids.

898

899 **How should I use FLOVENT HFA?**

- 900 1. It is important that you inhale each dose as your doctor has prescribed. The prescription label
901 provided by your pharmacist will usually tell you what dose to take and how often. If it
902 doesn't, or if you are not sure, ask your doctor or pharmacist. **DO NOT** inhale more doses or
903 use your FLOVENT HFA more often than your doctor has prescribed.
- 904 2. It may take 1 to 2 weeks or longer for this medicine to work, and it is very important that you
905 use it regularly. **Do not stop taking FLOVENT HFA, even if you are feeling better,**
906 **unless your doctor tells you to.**
- 907 3. If you miss a dose, just take your next scheduled dose when it is due. **Do not double the**
908 **dose.**
- 909 4. Your doctor may prescribe additional medicine (such as fast-acting bronchodilators) for
910 emergency relief if a sudden asthma attack occurs. Contact your doctor if:
 - 911 • an asthma attack does not respond to the additional medicine or
 - 912 • you need more of the additional medicine than usual.
- 913 5. If you also use another medicine by inhalation, you should ask your doctor for instructions on
914 when to use it while you are also using FLOVENT HFA.

915

916 **What are the possible side effects of FLOVENT HFA?**

917 Common side effects in adults and children using FLOVENT HFA include:

- 918 • a cold or upper respiratory tract infection
- 919 • throat irritation

- 920 • headache
- 921 • thrush (fungal infection) in the mouth and throat
- 922 Other common side effects in children include:
- 923 • fever
- 924 • diarrhea
- 925 • ear infection
- 926 • vomiting
- 927 • bronchitis
- 928 • inflammation of the nose and throat
- 929 • viral infection

930 Tell your doctor if you have any side effect that bothers you or that does not go away. These
 931 are not all the possible side effects of FLOVENT HFA. For more information ask your doctor or
 932 pharmacist.

933 Call your doctor for medical advice about side effects. You may report side effects to FDA at
 934 1-800-FDA-1088.

935

936 **What are the ingredients in FLOVENT HFA?**

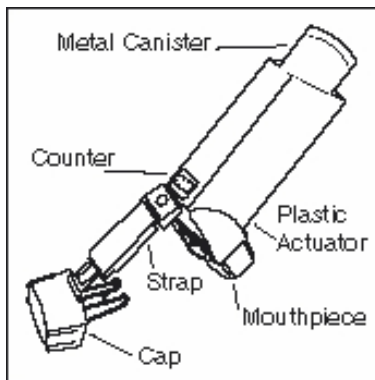
937 Active ingredient: fluticasone propionate (micronized)

938 Inactive ingredient: propellant HFA-134a

939

940 **Instructions for Using FLOVENT HFA**

941 **The parts of your FLOVENT HFA**



942 **Figure 1**

944 There are 2 main parts to your FLOVENT HFA
 945 inhaler—the metal canister that holds the medicine and the
 946 dark orange plastic actuator that sprays the medicine from
 947 the canister (see Figure 1).

948 The canister has a counter to show how many sprays of
 949 medicine you have left. The number shows through a
 950 window in the back of the actuator. The counter starts at
 951 124. The number will count down by 1 each time you spray
 952 the inhaler. The counter will stop counting at 000.

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

955 The mouthpiece of the actuator is covered by a cap. A strap on this cap keeps it attached to the
 956 actuator.

957 **Do not use the actuator with a canister of medicine from any other inhaler. And do not**
958 **use a FLOVENT HFA canister with an actuator from any other inhaler.**

959

960 **Using your FLOVENT HFA**

- 961 • The inhaler should be at room temperature before you use it.
- 962 • Take your FLOVENT HFA inhaler out of the moisture-protective foil pouch just before you
963 use it for the first time. Safely throw away the foil pouch and the drying packet that comes
964 inside the pouch.

- 965 • **Priming the inhaler:**

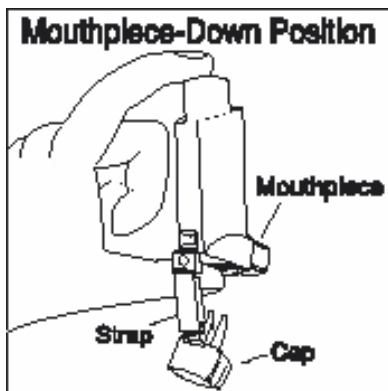
966 **Before you use FLOVENT HFA for the first time, you must prime the inhaler so that**
967 **you will get the right amount of medicine when you use it.** To prime the inhaler, take the
968 cap off the mouthpiece and shake the inhaler well for 5 seconds. Then spray the inhaler into
969 the air away from your face. **Avoid spraying in eyes.** Shake and spray the inhaler like this 3
970 more times to finish priming it. The counter should now read 120.

971 You must prime the inhaler again if you have not used it in more than 7 days or if you
972 drop it. Take the cap off the mouthpiece and shake the inhaler well for 5 seconds. Then spray
973 it 1 time into the air away from your face.

- 974 • An adult should watch a child use the inhaler to be sure it is used correctly. If a child needs
975 help using the inhaler, an adult should help the child use the inhaler with or without a holding
976 chamber attached to a facemask. The adult should follow the instructions that came with the
977 holding chamber.

978

979 Read the following 7 steps before using FLOVENT HFA and follow them at each use. If you
980 have any questions, ask your doctor or pharmacist.



981 **Figure 2**

- 983 1. **Take the cap off the mouthpiece of the actuator** (see
984 Figure 2).
985 Look inside the mouthpiece for foreign objects, and
986 take out any you see.
987 Make sure the canister fits firmly in the actuator.
988 **Shake the inhaler well** for 5 seconds.
- 989 2. Hold the inhaler with the mouthpiece down (see Figure
990 2). **Breathe out through your mouth** and push as
991 much air from your lungs as you can. Put the
992 mouthpiece in your mouth and close your lips around it.

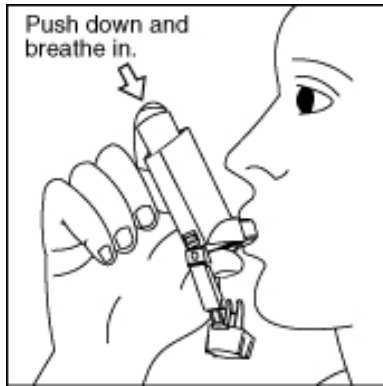


Figure 3

- 995 3. Push the top of the canister all the way down while you
996 breathe in deeply and slowly through your mouth (see
997 Figure 3)
998 Right after the spray comes out, take your finger off
999 the canister. After you have breathed in all the way,
1000 take the inhaler out of your mouth and close your
1001 mouth.
- 1002 4. **Hold your breath as long as you can**, up to 10
1003 seconds. Then breathe normally.
- 1004 5. **Wait about 30 seconds and shake the inhaler well** for
1005 5 seconds. Repeat steps 2 through 4.
- 1006 6. After you finish taking this medicine, rinse your mouth
1007 with water. Spit out the water. Do not swallow it.
- 1008 7. Put the cap back on the mouthpiece after each time you
1009 use the inhaler. Make sure it snaps firmly into place.

1010 **Cleaning your FLOVENT HFA**

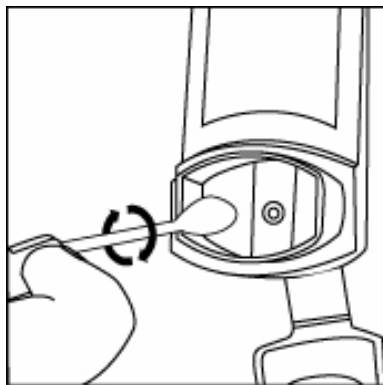


Figure 4

- 1013 Clean the inhaler at least once a week after your
1014 evening dose. It is important to keep the canister and
1015 plastic actuator clean so the medicine will not build-up
1016 and block the spray.
- 1017 1. Take the cap off the mouthpiece. The strap on the cap
1018 will stay attached to the actuator. Do not take the
1019 canister out of the plastic actuator.
 - 1020 2. Use a clean cotton swab dampened with water to clean
1021 the small circular opening where the medicine sprays
1022 out of the canister. Gently twist the swab in a circular
1023 motion to take off any medicine (see Figure 4). Repeat
1024 with a new swab dampened with water to take off any
1025 medicine still at the opening.
 - 1026 3. Wipe the inside of the mouthpiece with a clean tissue
1027 dampened with water. Let the actuator air-dry
1028 overnight.
 - 1029 4. Put the cap back on the mouthpiece after the actuator
1030 has dried.

1031 **Storing your FLOVENT HFA**

- 1032 **Store at room temperature with the mouthpiece down.**
1033 Keep out of reach of children.

1034 **Contents Under Pressure:** Do not puncture. Do not use or store near heat or open flame.
1035 Exposure to temperatures above 120°F may cause bursting. Never throw into fire or incinerator.
1036

1037 **Replacing your FLOVENT HFA**

- 1038 • **When the counter reads 020**, you should refill your prescription or ask your doctor if you
1039 need a refill of your prescription.
- 1040 • **When the counter reads 000**, throw the inhaler away. You should not keep using the inhaler
1041 because you will not receive the right amount of medicine.
- 1042 • **Do not use the inhaler** after the expiration date, which is on the packaging it comes in.
1043

1044 For more information go to www.floventdiskus.com or call 1-888-825-5249.

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