

Figure 3

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1524 Step 3. Put the mouthpiece cover back on after the actuator has dried.

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GlaxoSmithKline
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PHARMACIST—DETACH HERE AND GIVE MEDICATION GUIDE TO PATIENT

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MEDICATION GUIDE

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

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

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

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

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

- **ADVAIR HFA contains 2 medicines:**
 - **fluticasone propionate (the same medicine found in FLOVENT[®]),** an inhaled corticosteroid medicine. Inhaled corticosteroids help to decrease inflammation in the lungs. Inflammation in the lungs can lead to asthma symptoms.
 - **salmeterol (the same medicine found in SEREVENT[®]),** a long-acting beta₂-agonist medicine or LABA. LABA medicines are used in patients with asthma. LABA medicines help the muscles around the airways in your lungs stay relaxed to prevent symptoms, such as wheezing and shortness of breath. These symptoms can happen when the muscles around the airways tighten. This makes it hard to breathe. In severe cases, wheezing can stop your breathing and cause death if not treated right away.
- **In patients with asthma, LABA medicines, such as salmeterol (one of the medicines in ADVAIR HFA), may increase the chance of death from asthma problems.** In a large asthma study, more patients who used salmeterol died from asthma problems compared with patients who did not use salmeterol. It is not known whether fluticasone propionate, the other medicine in ADVAIR HFA, changes your chance of death from asthma problems seen with salmeterol. Talk with your healthcare provider about this risk and the benefits of treating your asthma with ADVAIR HFA.
- **ADVAIR HFA does not relieve sudden symptoms. Always have a short-acting beta₂-agonist medicine with you to treat sudden symptoms. If you do not have an inhaled, short-acting bronchodilator, contact your healthcare provider to have one prescribed for you.**
- **Do not stop using ADVAIR HFA unless told to do so by your healthcare provider because your symptoms might get worse.**

- 1589 • **ADVAIR HFA should be used only if your healthcare provider decides that another**
1590 **asthma-controller medicine alone does not control your asthma or that you need 2**
1591 **asthma-controller medicines.**
1592
1593 • **Call your healthcare provider if breathing problems worsen over time while using**
1594 **ADVAIR HFA. You may need different treatment.**
1595
1596 • **Get emergency medical care if:**
1597 • **breathing problems worsen quickly, and**
1598 • **you use your short-acting beta₂-agonist medicine, but it does not relieve your**
1599 **breathing problems.**
1600

1601 **What is ADVAIR HFA?**

1602 ADVAIR HFA combines an inhaled corticosteroid medicine, fluticasone propionate (the same
1603 medicine found in FLOVENT) and a long-acting beta₂-agonist medicine, salmeterol (the same
1604 medicine found in SEREVENT). ADVAIR HFA is used for asthma as follows:
1605

1606 ADVAIR HFA is used long term, twice a day to control symptoms of asthma, and prevent
1607 symptoms such as wheezing in adolescents and adults 12 years of age and older.
1608

1609 **ADVAIR HFA contains salmeterol (the same medicine found in SEREVENT). Because**
1610 **LABA medicines, such as salmeterol, may increase the chance of death from asthma**
1611 **problems, ADVAIR HFA is not for adults and children with asthma who:**

- 1612 • are well controlled with another asthma-controller medicine, such as a low to medium
1613 dose of an inhaled corticosteroid medicine
1614 • only need short-acting beta₂-agonist medicines once in awhile
1615

1616 **What should I tell my healthcare provider before using ADVAIR HFA?**

1617 **Tell your healthcare provider about all of your health conditions, including if you:**

- 1618 • **have heart problems**
1619 • **have high blood pressure**
1620 • **have seizures**
1621 • **have thyroid problems**
1622 • **have diabetes**
1623 • **have liver problems**
1624 • **have osteoporosis**
1625 • **have an immune system problem**
1626 • **are pregnant or planning to become pregnant.** It is not known if ADVAIR HFA may harm
1627 your unborn baby.

- 1628 • **are breastfeeding.** It is not known if ADVAIR HFA passes into your milk and if it can harm
1629 your baby.
- 1630 • **are allergic to ADVAIR HFA any other medicines**
- 1631 • **are exposed to chickenpox or measles**

1632
1633 Tell your healthcare provider about all the medicines you take including prescription and
1634 non-prescription medicines, vitamins, and herbal supplements. ADVAIR HFA and certain other
1635 medicines may interact with each other. This may cause serious side effects. Especially, tell your
1636 healthcare provider if you take ritonavir. The anti-HIV medicines NORVIR[®] (ritonavir capsules)
1637 Soft Gelatin, NORVIR (ritonavir oral solution), and KALETRA[®] (lopinavir/ritonavir) Tablets
1638 contain ritonavir.

1639
1640 Know the medicines you take. Keep a list and show it to your healthcare provider and pharmacist
1641 each time you get a new medicine.

1642
1643 **How do I use ADVAIR HFA?**
1644 **See the step-by-step instructions for using ADVAIR HFA at the end of this Medication**
1645 **Guide.** Do not use the ADVAIR HFA unless your healthcare provider has taught you and you
1646 understand everything. Ask your healthcare provider or pharmacist if you have any questions.

- 1647
1648 • Use ADVAIR HFA exactly as prescribed. **Do not use ADVAIR HFA more often than**
1649 **prescribed.** ADVAIR HFA comes in 3 strengths. Your healthcare provider will prescribe the
1650 one that is best for your condition.
- 1651
1652 • The usual dosage of ADVAIR HFA is 2 inhalations twice a day (morning and evening). The
1653 2 doses should be about 12 hours apart. Rinse your mouth with water after using ADVAIR
1654 HFA.
- 1655
1656 • If you miss a dose of ADVAIR HFA, just skip that dose. Take your next dose at your usual
1657 time. Do not take 2 doses at one time.
- 1658
1659 • **While you are using ADVAIR HFA twice a day, do not use other medicines that contain**
1660 **a long-acting beta₂-agonist or LABA for any reason. Other LABA-containing medicines**
1661 **include ADVAIR DISKUS[®] (fluticasone propionate and salmeterol inhalation powder),**
1662 **SEREVENT[®] DISKUS[®] (salmeterol xinafoate inhalation powder), or FORADIL[®]**
1663 **AEROLIZER[™] (formoterol fumarate inhalation powder).**
- 1664
1665 • Do not change or stop any of your medicines used to control or treat your breathing
1666 problems. Your healthcare provider will adjust your medicines as needed.

1667

- 1668 • Make sure you always have a short-acting beta₂-agonist medicine with you. Use your
1669 short-acting beta₂-agonist medicine if you have breathing problems between doses of
1670 ADVAIR HFA.
1671
- 1672 • **Call your healthcare provider or get medical care right away if:**
- 1673 • your breathing problems worsen with ADVAIR HFA
 - 1674 • you need to use your short-acting beta₂-agonist medicine more often than usual
 - 1675 • your short-acting beta₂-agonist medicine does not work as well for you at relieving
1676 symptoms
 - 1677 • you need to use 4 or more inhalations of your short-acting beta₂-agonist medicine for 2 or
1678 more days in a row
 - 1679 • you use 1 whole canister of your short-acting beta₂-agonist medicine in 8 weeks' time
 - 1680 • your peak flow meter results decrease. Your healthcare provider will tell you the numbers
1681 that are right for you.
 - 1682 • you have asthma and your symptoms do not improve after using ADVAIR HFA regularly
1683 for 1 week
- 1684

1685 **What are the possible side effects with ADVAIR HFA?**

- 1686 • **ADVAIR HFA contains salmeterol (the same medicine found in SEREVENT). In**
1687 **patients with asthma, LABA medicines, such as salmeterol, may increase the chance of**
1688 **death from asthma problems.** See “What is the most important information I should know
1689 about ADVAIR HFA?”
- 1690

1691 **Other possible side effects with ADVAIR HFA include:**

- 1692 • **serious allergic reactions including rash; hives; swelling of the face, mouth, and tongue;**
1693 **and breathing problems.** Call your healthcare provider or get emergency medical care if
1694 you get any symptoms of a serious allergic reaction.
- 1695 • **increased blood pressure**
- 1696 • **a fast and irregular heartbeat**
- 1697 • **chest pain**
- 1698 • **headache**
- 1699 • **tremor**
- 1700 • **nervousness**
- 1701 • **immune system effects and a higher chance for infections**
- 1702 • **lower bone mineral density.** This may be a problem for people who already have a higher
1703 chance for low bone density (osteoporosis).
- 1704 • **eye problems including glaucoma and cataracts.** You should have regular eye exams
1705 while using ADVAIR HFA.
- 1706 • **slowed growth in children.** A child's growth should be checked often.
- 1707 • **throat irritation**

1708
1709 Tell your healthcare provider about any side effect that bothers you or that does not go away.

1710
1711 These are not all the side effects with ADVAIR HFA. Ask your healthcare provider or
1712 pharmacist for more information.

1713
1714 **How do I store ADVAIR HFA?**

- 1715 • **Store ADVAIR HFA at room temperature with the mouthpiece down.**
- 1716 • **Do not puncture the canister. Do not use or store ADVAIR HFA near heat or an open**
1717 **flame. Never throw it into a fire or incinerator.**
- 1718 • **Keep ADVAIR HFA and all medicines out of the reach of children.**

1719
1720 **General Information about ADVAIR HFA**

1721 Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not
1722 use ADVAIR HFA for a condition for which it was not prescribed. Do not give your ADVAIR
1723 HFA to other people, even if they have the same condition. It may harm them.

1724 This Medication Guide summarizes the most important information about ADVAIR HFA. If you
1725 would like more information, talk with your healthcare provider or pharmacist. You can ask your
1726 healthcare provider or pharmacist for information about ADVAIR HFA that was written for
1727 healthcare professionals. You can also contact the company that makes ADVAIR HFA (toll free)
1728 at 1-888-825-5249 or at www.advair.com.

1729

1730 **Instructions for Using Your ADVAIR HFA**

1731 Follow the instructions below for using your ADVAIR HFA.

1732 Take your ADVAIR HFA inhaler out of the moisture-protective foil pouch before you use it for
1733 the first time. Safely throw away the foil pouch and the drying packet that comes inside the
1734 pouch.

1735 The inhaler should be at room temperature before you use it.

1736 **The purple actuator that comes with ADVAIR HFA should not be used with any other**
1737 **product canisters. Actuators that come with other products should not be used with an**
1738 **ADVAIR HFA canister.**

1739 **Prime the inhaler** before using it for the first time. To prime the inhaler, shake it well for
1740 5 seconds. Then spray it 1 time into the air away from your face. Shake and spray the inhaler like
1741 this 3 more times to finish priming it. **Avoid spraying in eyes.**

1742 If you have not used your inhaler in more than 4 weeks or if you have dropped it, shake it well
1743 for 5 seconds and spray it 1 time into the air away from your face.

1744 **Shake the inhaler well** for 5 seconds just before before each use. The inhaler should be at room
1745 temperature before you use it.

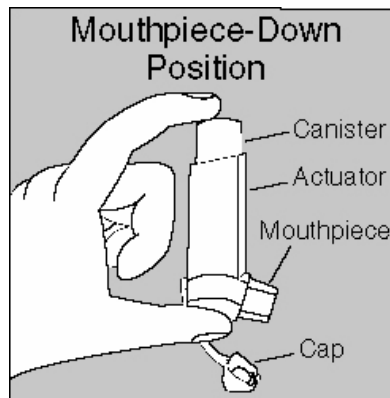
1746 **1.** Take the cap off the mouthpiece (see Figure 1). The strap on the cap will stay attached to the
1747 actuator.

1748 Look for foreign objects inside the inhaler before each use, especially if the strap is no longer
1749 attached to the actuator or if the cap is not being used to cover the mouthpiece.

1750 Make sure the canister is fully and firmly inserted into the actuator.

1751 **Shake the inhaler well** for 5 seconds right before each use.

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1756 **2. Breathe out fully through your mouth,** pushing as much air out of your lungs as you can.

1757 Put the mouthpiece all the way into your mouth. Hold the inhaler with the mouthpiece down
1758 (see Figure 1). Close your lips around it.

1759 **3.** It is important to get the medicine in the spray into your lungs where it works. To do this, you
1760 need to **inhale the spray at the same time you take in a slow, deep breath.**

1761 So, just after starting to take in a slow, deep breath through your mouth, press down firmly on
1762 the top of the metal canister (see Figure 2) and keep breathing in through your mouth.

1763 Take your finger off the canister right after the spray comes out of the canister. Take the
1764 mouthpiece out of your mouth after you have finished breathing in.

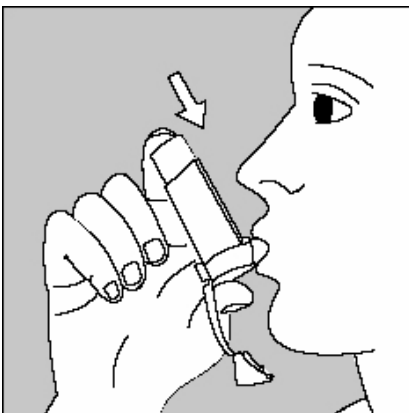


Figure 2

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1767 4. **Hold your breath as long as you can**, up to 10 seconds. Then breathe normally.

1768 5. **Wait about 30 seconds and shake** the inhaler again. Repeat steps 2 through 4.

1769 6. **Put the cap back on the mouthpiece after each time you use the inhaler.**

1770 7. After you finish taking this medicine, rinse your mouth with water. Spit out the water. Do not
1771 swallow it.

1772 8. Never put the canister in water to find out how much medicine is left in the canister (“float
1773 test”).

1774 9. You should keep track of the number of inhalations used from your inhaler. **Then throw away**
1775 **the inhaler after you have used 120 inhalations.** Even though the canister might not be empty
1776 and will keep spraying, you might not get the right amount of medicine in each inhalation.
1777 Before you get to 120 inhalations, ask your doctor if you need to refill your prescription.

1778 **Do not** use after the expiration date, which is shown as “EXP” on the product label and box.

1779 **Cleaning your ADVAIR HFA Inhalation Aerosol:**

1780 Clean the inhaler at least once a week after your evening dose. Keeping the canister and plastic
1781 actuator clean is important to prevent medicine build-up.

1782 Step 1. Take the cap off the mouthpiece. The strap on the cap will stay attached to the actuator.
1783 cap. Do not take the canister out of the plastic actuator.

1784 Step 2. Use a dry cotton swab to clean the small circular opening where the medicine sprays out
1785 of the canister. Carefully twist the swab in a circular motion to take off any medicine (see Figure
1786 3). Then wipe the inside of the mouthpiece with a clean tissue dampened with water. Let the
1787 actuator air-dry overnight.

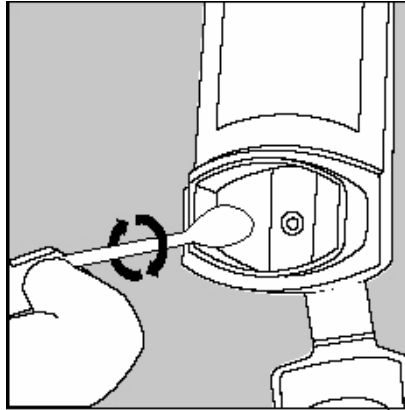


Figure 3

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1790 Step 3. Put the mouthpiece cover back on after the actuator has dried.

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