

MEDICATION GUIDE

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

**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 this Medication Guide carefully before you start to use ADVAIR HFA Inhalation Aerosol.

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

Read the new Medication Guide that comes with each refill of your prescription because there may be new information.

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 (LABA) medicine. 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**

1669 inhaled, short-acting bronchodilator, contact your healthcare provider to have one
1670 prescribed for you.

- 1671 • Do not stop using ADVAIR HFA unless told to do so by your healthcare provider
1672 because your symptoms might get worse.
- 1673 • ADVAIR HFA should be used only if your healthcare provider decides that another
1674 asthma-controller medicine alone does not control your asthma or that you need 2
1675 asthma-controller medicines.
- 1676 • Call your healthcare provider if breathing problems worsen over time while using
1677 ADVAIR HFA. You may need different treatment.
- 1678 • Get emergency medical care if:
 - 1679 • breathing problems worsen quickly, and
 - 1680 • you use your short-acting beta₂-agonist medicine, but it does not relieve your
1681 breathing problems.

1683 What is ADVAIR HFA?

1684 ADVAIR HFA combines an inhaled corticosteroid medicine, fluticasone propionate (the same
1685 medicine found in FLOVENT) and a LABA medicine, salmeterol (the same medicine found in
1686 SEREVENT).

1687 ADVAIR HFA is used long term, twice a day to control symptoms of asthma, and prevent
1688 symptoms such as wheezing in adults and adolescents 12 years of age and older.

1689 **ADVAIR HFA contains salmeterol (the same medicine found in SEREVENT). Because
1690 LABA medicines, such as salmeterol, may increase the chance of death from asthma
1691 problems, ADVAIR HFA is not for adults and children with asthma who:**

- 1692 • are well controlled with another asthma-controller medicine, such as a low to medium dose
1693 of an inhaled corticosteroid medicine
- 1694 • only need short-acting beta₂-agonist medicines once in awhile

1696 Who should not use ADVAIR HFA?

1697 Do not use ADVAIR HFA:

- 1698 • to treat sudden severe symptoms of asthma
- 1699 • if you are allergic to any of the ingredients in ADVAIR HFA. See the end of this Medication
1700 Guide for a list of ingredients in ADVAIR HFA.

1702 What should I tell my healthcare provider before using ADVAIR HFA?

1703 Tell your healthcare provider about all of your health conditions, including if you:

- 1704 • have heart problems
- 1705 • have high blood pressure
- 1706 • have seizures
- 1707 • have thyroid problems

- 1708 • **have diabetes**
- 1709 • **have liver problems**
- 1710 • **have osteoporosis**
- 1711 • **have an immune system problem**
- 1712 • **are pregnant or planning to become pregnant.** It is not known if ADVAIR HFA may harm
- 1713 your unborn baby.
- 1714 • **are breastfeeding.** It is not known if ADVAIR HFA passes into your milk and if it can harm
- 1715 your baby.
- 1716 • **are allergic to ADVAIR HFA or any other medicines**
- 1717 • **are exposed to chickenpox or measles**
- 1718 Tell your healthcare provider about all the medicines you take including prescription and
- 1719 non-prescription medicines, vitamins, and herbal supplements. ADVAIR HFA and certain other
- 1720 medicines may interact with each other. This may cause serious side effects. Especially, tell your
- 1721 healthcare provider if you take ritonavir. The anti-HIV medicines NORVIR[®] (ritonavir capsules)
- 1722 Soft Gelatin, NORVIR (ritonavir oral solution), and KALETRA[®] (lopinavir/ritonavir) Tablets
- 1723 contain ritonavir.
- 1724 Know the medicines you take. Keep a list and show it to your healthcare provider and
- 1725 pharmacist each time you get a new medicine.

How do I use ADVAIR HFA?

- 1728 **See the step-by-step instructions for using ADVAIR HFA at the end of this Medication**
- 1729 **Guide.** Do not use ADVAIR HFA unless your healthcare provider has taught you and you
- 1730 understand everything. Ask your healthcare provider or pharmacist if you have any questions.
- 1731 • Use ADVAIR HFA exactly as prescribed. **Do not use ADVAIR HFA more often than**
 - 1732 **prescribed.** ADVAIR HFA comes in 3 strengths. Your healthcare provider has prescribed the
 - 1733 one that is best for your condition.
 - 1734 • The usual dose of ADVAIR HFA is 2 inhalations twice a day (morning and evening). The 2
 - 1735 doses should be about 12 hours apart. Rinse your mouth with water after using ADVAIR
 - 1736 HFA.
 - 1737 • If you miss a dose of ADVAIR HFA, just skip that dose. Take your next dose at your usual
 - 1738 time. Do not take 2 doses at one time.
 - 1739 • **While you are using ADVAIR HFA twice a day, do not use other medicines that contain**
 - 1740 **a LABA for any reason. Other LABA-containing medicines include ADVAIR DISKUS[®]**
 - 1741 **(fluticasone propionate and salmeterol inhalation powder), SEREVENT[®] DISKUS[®]**
 - 1742 **(salmeterol xinafoate inhalation powder), FORADIL[®] AEROLIZER[®] (formoterol**
 - 1743 **fumarate inhalation powder), SYMBICORT[®] (budesonide and formoterol fumarate**
 - 1744 **dihydrate) Inhalation Aerosol, PERFOROMIST[™] (formoterol fumarate) Inhalation**
 - 1745 **Solution, and BROVANA[™] (arformoterol tartrate) Inhalation Solution.**

- 1746 • Do not change or stop any of your medicines used to control or treat your breathing problems.
- 1747 Your healthcare provider will adjust your medicines as needed.
- 1748 • Make sure you always have a short-acting beta₂-agonist medicine with you. Use your
- 1749 short-acting beta₂-agonist medicine if you have breathing problems between doses of
- 1750 ADVAIR HFA.
- 1751 • **Call your healthcare provider or get medical care right away if:**
- 1752 • your breathing problems worsen with ADVAIR HFA
- 1753 • you need to use your short-acting beta₂-agonist medicine more often than usual
- 1754 • your short-acting beta₂-agonist medicine does not work as well for you at relieving
- 1755 symptoms
- 1756 • you need to use 4 or more inhalations of your short-acting beta₂-agonist medicine for 2 or
- 1757 more days in a row
- 1758 • you use 1 whole canister of your short-acting beta₂-agonist medicine in 8 weeks' time
- 1759 • your peak flow meter results decrease. Your healthcare provider will tell you the numbers
- 1760 that are right for you.
- 1761 • you have asthma and your symptoms do not improve after using ADVAIR HFA regularly
- 1762 for 1 week
- 1763

What are the possible side effects with ADVAIR HFA?

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

Other possible side effects with ADVAIR HFA include:

- 1770 • **serious allergic reactions including rash; hives; swelling of the face, mouth, and tongue;**
- 1771 **and breathing problems.** Call your healthcare provider or get emergency medical care if you
- 1772 get any symptoms of a serious allergic reaction.
- 1773 • **increased blood pressure**
- 1774 • **a fast and irregular heartbeat**
- 1775 • **chest pain**
- 1776 • **headache**
- 1777 • **tremor**
- 1778 • **nervousness**
- 1779 • **immune system effects and a higher chance for infections**
- 1780 • **lower bone mineral density.** This may be a problem for people who already have a higher
- 1781 chance for low bone density (osteoporosis).
- 1782 • **eye problems including glaucoma and cataracts.** You should have regular eye exams while
- 1783 using ADVAIR HFA.
- 1784 • **slowed growth in children.** A child's growth should be checked often.

- 1785 • **throat irritation**
- 1786 • **pneumonia.** ADVAIR HFA contains the same medicine found in ADVAIR DISKUS.
- 1787 ADVAIR DISKUS is used to treat people with asthma and people with chronic obstructive
- 1788 pulmonary disease (COPD). People with COPD have a higher chance of getting pneumonia.
- 1789 ADVAIR DISKUS may increase the chance of getting pneumonia. ADVAIR HFA has not
- 1790 been studied in people with COPD.

1791 **Common side effects of ADVAIR HFA include upper respiratory tract infection and**

1792 **headache.**

1793 Tell your healthcare provider about any side effect that bothers you or that does not go away.

1794 These are not all the side effects with ADVAIR HFA. Ask your healthcare provider or

1795 pharmacist for more information.

1796 Call your doctor for medical advice about side effects. You may report side effects to FDA at

1797 1-800-FDA-1088.

1798

1799 **How should I store ADVAIR HFA?**

1800 Store at room temperature with the mouthpiece down.

1801 **Contents Under Pressure:** Do not puncture. Do not use or store near heat or open flame.

1802 Exposure to temperatures above 120°F may cause bursting.

1803 Do not throw into fire or an incinerator.

1804 **Keep ADVAIR HFA and all medicines out of the reach of children.**

1805

1806 **General information about ADVAIR HFA**

1807 Medicines are sometimes prescribed for purposes other than those listed in a Medication

1808 Guide. Do not use ADVAIR HFA for a condition for which it was not prescribed. Do not give

1809 your ADVAIR HFA to other people, even if they have the same condition that you have. It may

1810 harm them.

1811 This Medication Guide summarizes the most important information about ADVAIR HFA. If

1812 you would like more information, talk with your healthcare provider or pharmacist. You can ask

1813 your healthcare provider or pharmacist for information about ADVAIR HFA that was written for

1814 healthcare professionals. You can also contact the company that makes ADVAIR HFA (toll free)

1815 at 1-888-825-5249 or at www.advair.com.

1816

1817 **What are the ingredients in ADVAIR HFA?**

1818 Active ingredients: fluticasone propionate, salmeterol xinafoate

1819 Inactive ingredient: propellant HFA-134a

1820

1821 **How to use your ADVAIR HFA**

1822 **The parts of your ADVAIR HFA:**

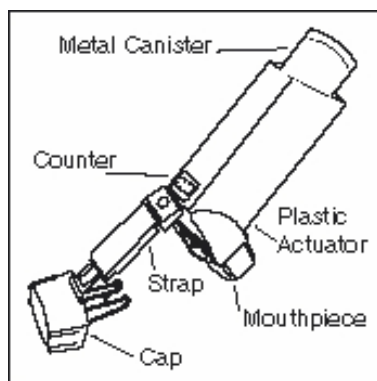


Figure 1

1825 There are 2 main parts to your ADVAIR HFA inhaler—
 1826 the metal canister that holds the medicine and the purple
 1827 plastic actuator that sprays the medicine from the canister
 1828 (see Figure 1).

1829 The inhaler also has a cap that covers the mouthpiece of
 1830 the actuator. The strap on the cap will stay attached to the
 1831 actuator.

1832 **Do not use the actuator with a canister of medicine**
 1833 **from any other inhaler. Do not use an ADVAIR HFA**
 1834 **canister with an actuator from any other inhaler.**

1835 The canister has a counter to show how many sprays of medicine you have left. The number
 1836 shows through a window in the back of the actuator.

1837 The counter starts at 124. The number will count down by 1 each time you spray the inhaler.
 1838 The counter will stop counting at 000.

1839 **Never try to change the numbers or take the counter off the metal canister.** The counter
 1840 cannot be reset, and it is permanently attached to the canister.

1841 **Before using your ADVAIR HFA:**

1842 Take the inhaler out of the foil pouch. Safely throw away the foil pouch and the drying packet
 1843 that comes inside the pouch. The counter should read 124.

1844 The inhaler should be at room temperature before you use it.

1845 Check each time to make sure the canister fits firmly in the plastic actuator. Also look into the
 1846 mouthpiece to make sure there are no foreign objects there, especially if the strap is no longer
 1847 attached to the actuator or if the cap is not being used to cover the mouthpiece.

1848 **Priming your ADVAIR HFA:**

1849 Before you use ADVAIR HFA for the first time, you must prime the inhaler so that you will
 1850 get the right amount of medicine when you use it. To prime the inhaler, take the cap off the
 1851 mouthpiece and shake the inhaler well for 5 seconds. Then spray it 1 time into the air away from
 1852 your face. Shake and spray the inhaler like this 3 more times to finish priming it. **Avoid**
 1853 **spraying in eyes.** The counter should now read 120.

1854 You must prime your inhaler again if you have not used it in more than 4 weeks or if you have
 1855 dropped it. Take the cap off the mouthpiece, shake the inhaler well for 5 seconds, and spray it
 1856 into the air away from your face. Shake and spray the inhaler like this 1 more time to finish
 1857 priming it.

1858 **Instructions for taking a dose from your ADVAIR HFA:**

1859 Read through the 7 steps below before using ADVAIR HFA. If you have any questions, ask
 1860 your doctor or pharmacist.

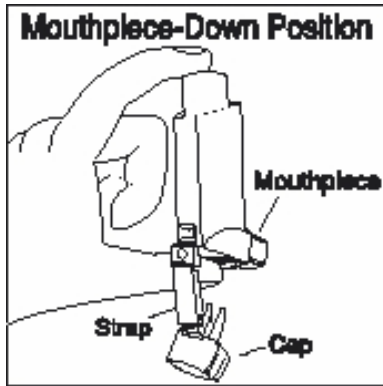


Figure 2

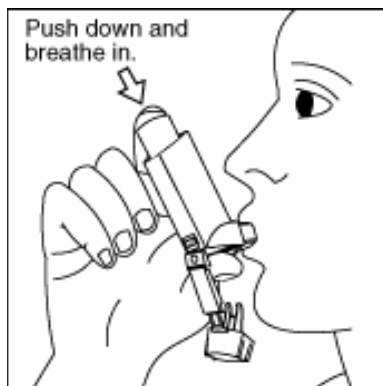


Figure 3

- 1866 1. Take the cap off the mouthpiece of the actuator. **Shake**
- 1867 **the inhaler well** for 5 seconds before each spray.
- 1868 2. Hold the inhaler with the mouthpiece down (see Figure
- 1869 2). **Breathe out through your mouth** and push as much
- 1870 air from your lungs as you can. Put the mouthpiece in
- 1871 your mouth and close your lips around it.
- 1872 3. **Push the top of the canister all the way down while**
- 1873 **you breathe in deeply and slowly through your**
- 1874 **mouth** (see Figure 3). Right after the spray comes out,
- 1875 take your finger off the canister. After you have breathed
- 1876 in all the way, take the inhaler out of your mouth and
- 1877 close your mouth.
- 1878 4. **Hold your breath as long as you can**, up to 10 seconds,
- 1879 then breathe normally.
- 1880 5. Wait about 30 seconds and **shake** the inhaler again for 5
- 1881 seconds. Repeat steps 2 through 4.
- 1882 6. After you finish taking this medicine, rinse your mouth
- 1883 with water. Spit out the water. Do not swallow it.
- 1884 7. Put the cap back on the mouthpiece after every time you
- 1885 use the inhaler, and make sure it snaps firmly into place.

When to replace your ADVAIR HFA:

- 1886 • **When the counter reads 020**, you should refill your prescription or ask your doctor if you
- 1887 need another prescription for ADVAIR HFA.
- 1888 • **Throw the inhaler away** when the counter reads 000. You should not keep using the inhaler
- 1889 when the counter reads 000 because you will not receive the right amount of medicine.
- 1890 • **Do not use the inhaler** after the expiration date, which is on the packaging it comes in.

How to clean your ADVAIR HFA:

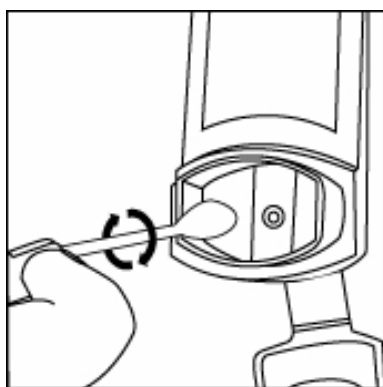


Figure 4

- 1895 Clean the inhaler at least once a week after your evening
- 1896 dose. It is important to keep the canister and plastic actuator
- 1897 clean so the medicine will not build-up and block the spray.
- 1898 1. Take the cap off the mouthpiece. The strap on the cap
 - 1899 will stay attached to the actuator. Do not take the
 - 1900 canister out of the plastic actuator.
 - 1901 2. Use a dry cotton swab to clean the small circular
 - 1902 opening where the medicine sprays out of the canister.
 - 1903 Carefully twist the swab in a circular motion to take off
 - 1904 any medicine (see Figure 4).

1905 3. Wipe the inside of the 1908 water. Let the actuator air-dry overnight.
1906 mouthpiece with a clean 1909 4. Put the cap back on the mouthpiece after the actuator has
1907 tissue dampened with 1910 dried.

1911

1912 **This Medication Guide has been approved by the U.S. Food and Drug Administration.**

1913

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1915 of GlaxoSmithKline.

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1918 GlaxoSmithKline or its products.

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1921

1922 GlaxoSmithKline

1923 Research Triangle Park, NC 27709

1924

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