

1592 a reduction in growth velocity when administered to pediatric patients. Physicians should closely
1593 follow the growth of children and adolescents taking corticosteroids by any route.

1594 **Ocular Effects:** Long-term use of inhaled corticosteroids may increase the risk of some
1595 eye problems (cataracts or glaucoma); regular eye examinations should be considered.

1596 **17.5 Risks Associated With Beta-Agonist Therapy**

1597 Patients should be informed of adverse effects associated with beta₂-agonists, such as
1598 palpitations, chest pain, rapid heart rate, tremor, or nervousness.

1599 **17.6 Medication Guide**

1600 **MEDICATION GUIDE**

1601 **ADVAIR [ad'vair] DISKUS[®] 100/50**

1602 **(fluticasone propionate 100 mcg and salmeterol 50 mcg inhalation powder)**

1603 **ADVAIR DISKUS[®] 250/50**

1604 **(fluticasone propionate 250 mcg and salmeterol 50 mcg inhalation powder)**

1605 **ADVAIR DISKUS[®] 500/50**

1606 **(fluticasone propionate 500 mcg and salmeterol 50 mcg inhalation powder)**

1607

1608 Read the Medication Guide that comes with ADVAIR DISKUS before you start using it and
1609 each time you get a refill. There may be new information. This Medication Guide does not take
1610 the place of talking to your healthcare provider about your medical condition or treatment.

1611

1612 **What is the most important information I should know about ADVAIR DISKUS?**

1613 • **ADVAIR DISKUS contains 2 medicines:**

- 1614 • **fluticasone propionate (the same medicine found in FLOVENT[®]),** an inhaled
1615 corticosteroid medicine. Inhaled corticosteroids help to decrease inflammation in the
1616 lungs. Inflammation in the lungs can lead to asthma symptoms.
- 1617 • **salmeterol (the same medicine found in SEREVENT[®]),** a long-acting beta₂-agonist
1618 medicine or LABA. LABA medicines are used in patients with asthma and chronic
1619 obstructive pulmonary disease (COPD). LABA medicines help the muscles around the
1620 airways in your lungs stay relaxed to prevent symptoms, such as wheezing and shortness
1621 of breath. These symptoms can happen when the muscles around the airways tighten.
1622 This makes it hard to breathe. In severe cases, wheezing can stop your breathing and
1623 cause death if not treated right away.

1624

- 1625 • **In patients with asthma, LABA medicines, such as salmeterol (one of the medicines in**
1626 **ADVAIR DISKUS), may increase the chance of death from asthma problems.** In a large
1627 asthma study, more patients who used salmeterol died from asthma problems compared with
1628 patients who did not use salmeterol. It is not known whether fluticasone propionate, the other
1629 medicine in ADVAIR DISKUS, changes your chance of death from asthma problems seen

1630 with salmeterol. Talk with your healthcare provider about this risk and the benefits of
1631 treating your asthma with ADVAIR DISKUS.

- 1632
- 1633 • **ADVAIR DISKUS does not relieve sudden symptoms. Always have a short-acting**
1634 **beta₂-agonist medicine with you to treat sudden symptoms. If you do not have an**
1635 **inhaled, short-acting bronchodilator, contact your healthcare provider to have one**
1636 **prescribed for you.**
 - 1637
 - 1638 • **Do not stop using ADVAIR DISKUS unless told to do so by your healthcare provider**
1639 **because your symptoms might get worse.**
 - 1640
 - 1641 • **ADVAIR DISKUS should be used only if your healthcare provider decides that another**
1642 **asthma-controller medicine alone does not control your asthma or that you need 2**
1643 **asthma-controller medicines.**
 - 1644
 - 1645 • **Call your healthcare provider if breathing problems worsen over time while using**
1646 **ADVAIR DISKUS. You may need different treatment.**
 - 1647
 - 1648 • **Get emergency medical care if:**
 - 1649 • **breathing problems worsen quickly, and**
 - 1650 • **you use your short-acting beta₂-agonist medicine, but it does not relieve your**
1651 **breathing problems.**

1653 **What is ADVAIR DISKUS?**

1654 ADVAIR DISKUS combines an inhaled corticosteroid medicine, fluticasone propionate (the
1655 same medicine found in FLOVENT) and a long-acting beta₂-agonist medicine, salmeterol (the
1656 same medicine found in SEREVENT). ADVAIR DISKUS is used for asthma and chronic
1657 obstructive pulmonary disease (COPD) as follows:

1659 **Asthma**

1660 ADVAIR DISKUS is used long term, twice a day to control symptoms of asthma and to prevent
1661 symptoms such as wheezing in adults and children ages 4 and older.

1662

1663 **ADVAIR DISKUS contains salmeterol (the same medicine found in SEREVENT). Because**
1664 **LABA medicines, such as salmeterol, may increase the chance of death from asthma**
1665 **problems, ADVAIR DISKUS is not for adults and children with asthma who:**

- 1666 • are well controlled with another asthma-controller medicine such as a low to medium
1667 dose of an inhaled corticosteroid medicine
- 1668 • only need short-acting beta₂-agonist medicines once in awhile

1669

1670 **Chronic Obstructive Pulmonary Disease**

1671 COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both. ADVAIR
1672 DISKUS 250/50 is used long term, twice a day to help improve lung function for better breathing
1673 in adults with COPD. ADVAIR DISKUS 250/50 has been shown to decrease the number of
1674 flare-ups and worsening of COPD symptoms (exacerbations).

1675

1676 **Who should not use ADVAIR DISKUS?**

1677 **Do not use ADVAIR DISKUS:**

- 1678 • to treat sudden, severe symptoms of asthma or COPD
- 1679 • if you have a severe allergy to milk proteins. Ask your doctor if you are not sure.

1680

1681 **What should I tell my healthcare provider before using ADVAIR DISKUS?**

1682 **Tell your healthcare provider about all of your health conditions, including if you:**

- 1683 • **have heart problems**
- 1684 • **have high blood pressure**
- 1685 • **have seizures**
- 1686 • **have thyroid problems**
- 1687 • **have diabetes**
- 1688 • **have liver problems**
- 1689 • **have osteoporosis**
- 1690 • **have an immune system problem**
- 1691 • **are pregnant or planning to become pregnant.** It is not known if ADVAIR DISKUS may
1692 harm your unborn baby.
- 1693 • **are breastfeeding.** It is not known if ADVAIR DISKUS passes into your milk and if it can
1694 harm your baby.
- 1695 • **are allergic to any of the ingredients in ADVAIR DISKUS, any other medicines, or food**
1696 **products. See the end of this Medication Guide for a complete list of the ingredients in**
1697 **ADVAIR DISKUS.**
- 1698 • **are exposed to chickenpox or measles**

1699

1700 Tell your healthcare provider about all the medicines you take including prescription and
1701 non-prescription medicines, vitamins, and herbal supplements. ADVAIR DISKUS and certain
1702 other medicines may interact with each other. This may cause serious side effects. Especially,
1703 tell your healthcare provider if you take ritonavir. The anti-HIV medicines NORVIR[®] (ritonavir
1704 capsules) Soft Gelatin, NORVIR (ritonavir oral solution), and KALETRA[®] (lopinavir/ritonavir)
1705 Tablets contain ritonavir.

1706

1707 Know the medicines you take. Keep a list and show it to your healthcare provider and pharmacist
1708 each time you get a new medicine.

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How do I use ADVAIR DISKUS?

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

- Children should use ADVAIR DISKUS with an adult’s help, as instructed by the child’s healthcare provider.
- Use ADVAIR DISKUS exactly as prescribed. **Do not use ADVAIR DISKUS more often than prescribed.** ADVAIR DISKUS comes in 3 strengths. Your healthcare provider will prescribe the one that is best for your condition.
- The usual dosage of ADVAIR DISKUS is 1 inhalation twice a day (morning and evening). The 2 doses should be about 12 hours apart. Rinse your mouth with water after using ADVAIR DISKUS.
- **If you take more ADVAIR DISKUS than your doctor has prescribed, get medical help right away if you have any unusual symptoms, such as worsening shortness of breath, chest pain, increased heart rate, or shakiness.**
- If you miss a dose of ADVAIR DISKUS, just skip that dose. Take your next dose at your usual time. Do not take 2 doses at one time.
- Do not use a spacer device with ADVAIR DISKUS.
- Do not breathe into ADVAIR DISKUS.
- **While you are using ADVAIR DISKUS twice a day, do not use other medicines that contain a long-acting beta₂-agonist or LABA for any reason. Ask your healthcare provider or pharmacist if any of your other medicines are LABA medicines.**
- Do not change or stop any of your medicines used to control or treat your breathing problems. Your healthcare provider will adjust your medicines as needed.
- Make sure you always have a short-acting beta₂-agonist medicine with you. Use your short-acting beta₂-agonist medicine if you have breathing problems between doses of ADVAIR DISKUS.
- **Call your healthcare provider or get medical care right away if:**
 - your breathing problems worsen with ADVAIR DISKUS

- 1750 • you need to use your short-acting beta₂-agonist medicine more often than usual
- 1751 • your short-acting beta₂-agonist medicine does not work as well for you at relieving
- 1752 symptoms
- 1753 • you need to use 4 or more inhalations of your short-acting beta₂-agonist medicine for 2 or
- 1754 more days in a row
- 1755 • you use 1 whole canister of your short-acting beta₂-agonist medicine in 8 weeks' time
- 1756 • your peak flow meter results decrease. Your healthcare provider will tell you the numbers
- 1757 that are right for you.
- 1758 • you have asthma and your symptoms do not improve after using ADVAIR DISKUS
- 1759 regularly for 1 week

1760

1761 **What are the possible side effects with ADVAIR DISKUS?**

- 1762 • **ADVAIR DISKUS contains salmeterol (the same medicine found in SEREVENT). In**
- 1763 **patients with asthma, LABA medicines, such as salmeterol, may increase the chance of**
- 1764 **death from asthma problems.** See “What is the most important information I should know
- 1765 about ADVAIR DISKUS?”
- 1766 • Patients with COPD have a higher chance of getting pneumonia. ADVAIR DISKUS may
- 1767 increase the chance of getting pneumonia. **Call your healthcare provider if you notice any**
- 1768 **of the following symptoms:**
 - 1769 • increase in mucus (sputum) production
 - 1770 • change in mucus color
 - 1771 • fever
 - 1772 • chills
 - 1773 • increased cough
 - 1774 • increased breathing problems.

1775

1776 **Other possible side effects with ADVAIR DISKUS include:**

- 1777 • **serious allergic reactions.** Call your healthcare provider or get emergency medical care if
- 1778 you get any of the following symptoms of a serious allergic reaction, including:
 - 1779 • rash
 - 1780 • hives
 - 1781 • swelling of the face, mouth, and tongue
 - 1782 • breathing problems
- 1783 • **increased blood pressure**
- 1784 • **a fast and irregular heartbeat**
- 1785 • **chest pain**
- 1786 • **headache**
- 1787 • **tremor**
- 1788 • **nervousness**
- 1789 • **weakened immune system and a higher chance of infections**

- 1790 • **lower bone mineral density.** This may be a problem for people who already have a higher
1791 chance of low bone density (osteoporosis).
1792 • **eye problems including glaucoma and cataracts.** You should have regular eye exams
1793 while using ADVAIR DISKUS.
1794 • **slowed growth in children.** A child’s growth should be checked often.
1795

1796 **The most common side effects with ADVAIR DISKUS include:**

1797 **Asthma in adults and children:**

- 1798 • upper respiratory tract infection
1799 • throat irritation
1800 • hoarseness and voice changes
1801 • thrush in the mouth and throat
1802 • bronchitis
1803 • cough
1804 • headache
1805 • nausea and vomiting

1806 In children with asthma, infections in the ear, nose, and throat are also common.
1807

1808 **COPD:**

- 1809 • thrush in the mouth and throat
1810 • throat irritation
1811 • hoarseness and voice changes
1812 • viral respiratory infections
1813 • headache
1814 • muscle and bone pain
1815

1816 Tell your healthcare provider about any side effect that bothers you or that does not go away.
1817

1818 These are not all the side effects with ADVAIR DISKUS. Ask your healthcare provider or
1819 pharmacist for more information.
1820

1821 Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-
1822 800-FDA-1088.
1823

1824 **How do I store ADVAIR DISKUS?**

- 1825 • Store ADVAIR DISKUS at room temperature between 68° to 77° F (20° to 25° C). Keep in a
1826 dry place away from heat and sunlight.
1827 • Safely discard ADVAIR DISKUS 1 month after you remove it from the foil pouch, or after
1828 the dose indicator reads “0”, whichever comes first.
1829 • **Keep ADVAIR DISKUS and all medicines out of the reach of children.**

1830

1831 **General Information about ADVAIR DISKUS**

1832 Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not
1833 use ADVAIR DISKUS for a condition for which it was not prescribed. Do not give your
1834 ADVAIR DISKUS to other people, even if they have the same condition. It may harm them.

1835 This Medication Guide summarizes the most important information about ADVAIR DISKUS. If
1836 you would like more information, talk with your healthcare provider or pharmacist. You can ask
1837 your healthcare provider or pharmacist for information about ADVAIR DISKUS that was
1838 written for healthcare professionals. You can also contact the company that makes ADVAIR
1839 DISKUS (toll free) at 1-888-825-5249 or at www.advail.com.

1840

1841 **What are the ingredients in ADVAIR DISKUS?**

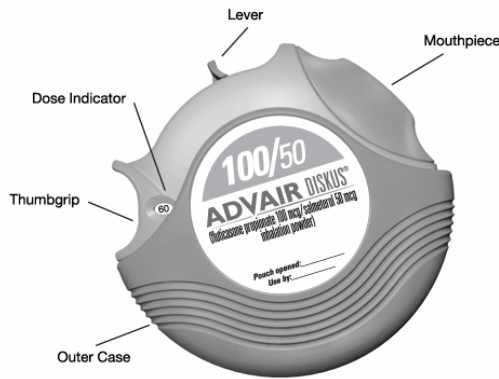
1842 Active ingredients: fluticasone propionate, salmeterol xinafoate

1843 Inactive ingredient: lactose (contains milk proteins)

1844

1845 **Instructions for Using ADVAIR DISKUS**

1846 Follow the instructions below for using your ADVAIR DISKUS. **You will breathe in (inhale)**
1847 **the medicine from the DISKUS[®].** If you have any questions, ask your healthcare provider or
1848 pharmacist.



1849

1850 Take ADVAIR DISKUS out of the box and foil pouch. Write the “**Pouch opened**” and “**Use**
1851 **by**” dates on the label on top of the DISKUS. The “**Use by**” date is **1 month from date of**
1852 **opening the pouch.**

- 1853
- The DISKUS will be in the closed position when the pouch is opened.
 - The **dose indicator** on the top of the DISKUS tells you how many doses are left. The dose indicator number will decrease each time you use the DISKUS. After you have used 55 doses from the DISKUS, the numbers 5 to 0 will appear in **red** to warn you that there are only a few doses left (*see Figure 1*). If you are using a “sample” DISKUS, the numbers 5 to 0 will appear in red after 23 doses.
- 1854
1855
1856
1857
1858



Figure 1

1859

1860

1861 Taking a dose from the DISKUS requires the following 3 simple steps: Open, Click, Inhale.

1862 **1. OPEN**

1863 Hold the DISKUS in one hand and put the thumb of your other hand on the **thumbgrip**. Push
1864 your thumb away from you as far as it will go until the mouthpiece appears and snaps into
1865 position (*see Figure 2*).



Figure 2

1866

1867

1868 **2. CLICK**

1869 Hold the DISKUS in a level, flat position with the mouthpiece towards you. Slide the **lever**
1870 away from you as far as it will go until it **clicks** (*see Figure 3*). The DISKUS is now ready to
1871 use.



Figure 3

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1873

1874

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Every time the **lever** is pushed back, a dose is ready to be inhaled. This is shown by a decrease in numbers on the dose counter. **To avoid releasing or wasting doses once the DISKUS is ready:**

- **Do not close the DISKUS.**
- **Do not tilt the DISKUS.**
- **Do not play with the lever.**
- **Do not move the lever more than once.**

1882

3. INHALE

1883

1884

1885

Before inhaling your dose from the DISKUS, breathe out (exhale) fully while holding the DISKUS level and away from your mouth (*see Figure 4*). **Remember, never breathe out into the DISKUS mouthpiece.**



Figure 4

1886

1887

1888 Put the mouthpiece to your lips (*see Figure 5*). Breathe in quickly and deeply through the
1889 DISKUS. Do not breathe in through your nose.



Figure 5

1890

1891

1892 Remove the DISKUS from your mouth. Hold your breath for about 10 seconds, or for as long
1893 as is comfortable. Breathe out slowly.

1894 The DISKUS delivers your dose of medicine as a very fine powder. Most patients can taste
1895 or feel the powder. Do not use another dose from the DISKUS if you do not feel or taste the
1896 medicine.

1897 Rinse your mouth with water after breathing-in the medicine. Spit the water out. Do not
1898 swallow.

1899 4. **Close the DISKUS when you are finished taking a dose so that the DISKUS will be**
1900 **ready for you to take your next dose.** Put your thumb on the thumbgrip and slide the
1901 thumbgrip back towards you as far as it will go (*see Figure 6*). The DISKUS will click shut.
1902 The lever will automatically return to its original position. The DISKUS is now ready for you
1903 to take your next scheduled dose, due in about 12 hours. (Repeat steps 1 to 4.)



1904
1905

Figure 6

Remember:

- Never breathe into the DISKUS.
- Never take the DISKUS apart.
- Always ready and use the DISKUS in a level, flat position.
- Do not use the DISKUS with a spacer device.
- After each dose, rinse your mouth with water and spit the water out. Do not swallow.
- Never wash the mouthpiece or any part of the DISKUS. **Keep it dry.**
- Always keep the DISKUS in a dry place.
- Never take an extra dose, even if you did not taste or feel the medicine.

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April 2008

ADD:4MG

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

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