

MEDICATION GUIDE

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ADVAIR [ad'vair] DISKUS[®]

1491

(fluticasone propionate and salmeterol inhalation powder)

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1493 **ADVAIR DISKUS**

1494 (fluticasone propionate 100 mcg and salmeterol 50 mcg inhalation powder)

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1496 **ADVAIR DISKUS**

1497 (fluticasone propionate 250 mcg and salmeterol 50 mcg inhalation powder)

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1499 **ADVAIR DISKUS**

1500 (fluticasone propionate 500 mcg and salmeterol 50 mcg inhalation powder)

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1502 Read the Medication Guide that comes with ADVAIR DISKUS before you start using it and
1503 each time you get a refill. There may be new information. This Medication Guide does not take
1504 the place of talking to your healthcare provider about your medical condition or treatment.

1505

1506 **What is the most important information I should know about ADVAIR DISKUS?**

1507 • **ADVAIR DISKUS contains 2 medicines:**

- 1508
- **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.
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- **salmeterol (the same medicine found in SEREVENT)**, a long-acting beta₂-agonist medicine or LABA. LABA medicines are used in patients with asthma and chronic obstructive pulmonary disease (COPD). 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.
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- **In patients with asthma, LABA medicines, such as salmeterol (one of the medicines in ADVAIR DISKUS), 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 DISKUS, 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 DISKUS.
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- **ADVAIR DISKUS 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.**
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- **Do not stop using ADVAIR DISKUS unless told to do so by your healthcare provider because your symptoms might get worse.**
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- **ADVAIR DISKUS** should be used only if your healthcare provider decides that another asthma-controller medicine alone does not control your asthma or that you need 2 asthma-controller medicines.
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- **Call your healthcare provider if breathing problems worsen over time while using ADVAIR DISKUS. You may need different treatment.**
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- **Get emergency medical care if:**
 - **breathing problems worsen quickly, and**
 - **you use your short-acting beta₂-agonist medicine, but it does not relieve your breathing problems.**
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1548 **What is ADVAIR DISKUS?**

1549 ADVAIR DISKUS combines an inhaled corticosteroid medicine, fluticasone propionate (the
1550 same medicine found in FLOVENT) and a long-acting beta₂-agonist medicine, salmeterol (the
1551 same medicine found in SEREVENT). ADVAIR DISKUS is used for asthma and chronic
1552 obstructive pulmonary disease (COPD) as follows:

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1554 **Asthma**

1555 ADVAIR DISKUS is used long term, twice a day to control symptoms of asthma, and prevent
1556 symptoms such as wheezing in adults and children ages 4 and older.

1557

1558 **ADVAIR DISKUS contains salmeterol (the same medicine found in SEREVENT). Because**
1559 **LABA medicines such as salmeterol may increase the chance of death from asthma**
1560 **problems, ADVAIR DISKUS is not for adults and children with asthma who:**

- 1561 • are well controlled with another asthma-controller medicine such as a low to medium
1562 dose of an inhaled corticosteroid medicine
- 1563 • only need short-acting beta₂-agonist medicines once in awhile

1564

1565 **Chronic Obstructive Pulmonary Disease (COPD)**

1566 ADVAIR DISKUS is used long term, twice a day in controlling symptoms of COPD and
1567 preventing wheezing in adults with COPD.

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1569 **What should I tell my healthcare provider before using ADVAIR DISKUS?**

1570 **Tell your healthcare provider about all of your health conditions, including if you:**

- 1571 • **have heart problems**
- 1572 • **have high blood pressure**
- 1573 • **have seizures**
- 1574 • **have thyroid problems**
- 1575 • **have diabetes**
- 1576 • **have liver problems**
- 1577 • **have osteoporosis**
- 1578 • **have an immune system problem**
- 1579 • **are pregnant or planning to become pregnant.** It is not known if ADVAIR DISKUS may
1580 harm your unborn baby.
- 1581 • **are breastfeeding.** It is not known if ADVAIR DISKUS passes into your milk and if it can
1582 harm your baby.
- 1583 • **are allergic to ADVAIR DISKUS, any other medicines, or food products**
- 1584 • **are exposed to chickenpox or measles**

1585

1586 Tell your healthcare provider about all the medicines you take including prescription and non-
1587 prescription medicines, vitamins, and herbal supplements. ADVAIR DISKUS and certain other

1588 medicines may interact with each other. This may cause serious side effects. Especially, tell your
1589 healthcare provider if you take ritonavir. The anti-HIV medicines NORVIR[®] (ritonavir capsules)
1590 Soft Gelatin, NORVIR (ritonavir oral solution), and KALETRA[®] (lopinavir/ritonavir) Tablets
1591 contain ritonavir.

1592
1593 Know the medicines you take. Keep a list and show it to your healthcare provider and pharmacist
1594 each time you get a new medicine.

1595

1596 **How do I use ADVAIR DISKUS?**

1597 **See the step-by-step instructions for using the ADVAIR DISKUS at the end of this**
1598 **Medication Guide.** Do not use the ADVAIR DISKUS unless your healthcare provider has
1599 taught you and you understand everything. Ask your healthcare provider or pharmacist if you
1600 have any questions.

1601

1602 • Children should use ADVAIR DISKUS with an adult's help, as instructed by the child's
1603 healthcare provider.

1604

1605 • Use ADVAIR DISKUS exactly as prescribed. **Do not use ADVAIR DISKUS more often**
1606 **than prescribed.** ADVAIR DISKUS comes in 3 strengths. Your healthcare provider will
1607 prescribe the one that is best for your condition.

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1609 • The usual dose of ADVAIR DISKUS is 1 inhalation twice a day (morning and evening). The
1610 2 doses should be about 12 hours apart. Rinse your mouth with water after using ADVAIR
1611 DISKUS.

1612

1613 • If you miss a dose of ADVAIR DISKUS, just skip that dose. Take your next dose at your
1614 usual time. Do not take 2 doses at one time.

1615

1616 • Do not use a spacer device with ADVAIR DISKUS.

1617

1618 • Do not breathe into ADVAIR DISKUS.

1619

1620 • **While you are using ADVAIR DISKUS twice a day, you should not use other medicines**
1621 **that contain a long-acting beta₂-agonist or LABA for any reason. Other LABA**
1622 **medicines include SEREVENT[®] DISKUS[®] (salmeterol xinafoate inhalation powder) or**
1623 **FORADIL[®] AEROLIZER[™] (formoterol fumarate inhalation powder).**

1624

1625 • Do not change or stop any of your medicines used to control or treat your breathing
1626 problems. Your healthcare provider will adjust your medicines as needed.

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- 1628 • Make sure you always have a short-acting beta₂-agonist medicine with you. Use your
1629 short-acting beta₂-agonist medicine if you have breathing problems between doses of
1630 ADVAIR DISKUS.
1631
1632 • **Call your healthcare provider or get medical care right away if:**
1633 • your breathing problems worsen with ADVAIR DISKUS
1634 • you need to use your short-acting beta₂-agonist medicine more often than usual
1635 • your short-acting beta₂-agonist medicine does not work as well for you at relieving
1636 symptoms
1637 • you need to use 4 or more inhalations of your short-acting beta₂-agonist medicine for 2 or
1638 more days in a row
1639 • you use 1 whole canister of your short-acting beta₂-agonist medicine in 8 weeks' time
1640 • your peak flow meter results decrease. Your healthcare provider will tell you the numbers
1641 that are right for you.
1642 • you have asthma and your symptoms do not improve after using ADVAIR DISKUS
1643 regularly for 1 week
1644

1645 **What are the possible side effects with ADVAIR DISKUS?**

- 1646 • **ADVAIR DISKUS contains salmeterol (the same medicine found in SEREVENT). In**
1647 **patients with asthma, LABA medicines such as salmeterol may increase the chance of**
1648 **death from asthma problems.** See “What is the most important information I should know
1649 about ADVAIR DISKUS?”
1650

1651 **Other possible side effects with ADVAIR DISKUS include:**

- 1652 • **serious allergic reactions including rash, hives, swelling of the face, mouth, and tongue,**
1653 **and breathing problems.** Call your healthcare provider or get emergency medical care if
1654 you get any symptoms of a serious allergic reaction.
1655 • **increased blood pressure**
1656 • **a fast and irregular heartbeat**
1657 • **chest pain**
1658 • **headache**
1659 • **tremor**
1660 • **nervousness**
1661 • **immune system effects and a higher chance for infections**
1662 • **lower bone mineral density.** This may be a problem for people who already have a higher
1663 chance for low bone density (osteoporosis).
1664 • **eye problems including glaucoma and cataracts.** You should have regular eye exams
1665 while using ADVAIR DISKUS.
1666 • **slowed growth in children.** A child's growth should be checked often.
1667 • **throat irritation**

1668
1669 Tell your healthcare provider about any side effect that bothers you or that does not go away.

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1671 These are not all the side effects with ADVAIR DISKUS. Ask your healthcare provider or
1672 pharmacist for more information.

1673
1674 **How do I store ADVAIR DISKUS?**

- 1675 • Store ADVAIR DISKUS at room temperature between 68° to 77° F (20° to 25° C). Keep in a
1676 dry place away from heat and sunlight.
- 1677 • Safely discard ADVAIR DISKUS 1 month after you remove it from the foil pouch, or after
1678 the dose indicator reads “0”, whichever comes first.
- 1679 • **Keep ADVAIR DISKUS and all medicines out of the reach of children.**

1680
1681 **General Information about ADVAIR DISKUS**

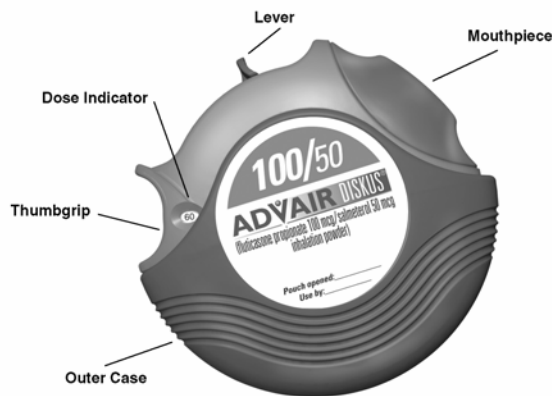
1682 Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not
1683 use ADVAIR DISKUS for a condition for which it was not prescribed. Do not give your
1684 ADVAIR DISKUS to other people, even if they have the same condition. It may harm them.

1685 This Medication Guide summarizes the most important information about ADVAIR DISKUS. If
1686 you would like more information, talk with your healthcare provider or pharmacist. You can ask
1687 your healthcare provider or pharmacist for information about ADVAIR DISKUS that was
1688 written for healthcare professionals. You can also contact the company that makes ADVAIR
1689 DISKUS (toll free) at 1-888-825-5249 or at www.advail.com.

1690
1691 **Instructions for Using ADVAIR DISKUS**

1692 Follow the instructions below for using your ADVAIR DISKUS. **You will breathe-in (inhale)**
1693 **the medicine from the DISKUS.** If you have any questions, ask your healthcare provider or
1694 pharmacist.

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How to Use Your ADVAIR DISKUS

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

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1702

- The DISKUS will be in the closed position when the pouch is opened.

1703

- 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.

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Figure 1

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

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1. **OPEN**

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Hold the DISKUS in one hand and put the thumb of your other hand on the **thumbgrip**.

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Push your thumb away from you as far as it will go until the mouthpiece appears and

1714

snaps into position (*see Figure 2*).



Figure 2

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1717 2. **CLICK**

1718 Hold the DISKUS in a level, flat position with the mouthpiece towards you. Slide the
1719 **lever** away from you as far as it will go until it **clicks** (*see Figure 3*). The DISKUS is
1720 now ready to use.



Figure 3

1721
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1723 Every time the **lever** is pushed back, a dose is ready to be inhaled. This is shown by a
1724 decrease in numbers on the dose counter. **To avoid releasing or wasting doses once the**
1725 **DISKUS is ready:**

- 1726 • **Do not close the DISKUS.**

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

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3. **INHALE**

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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.**



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Figure 4

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



Figure 5

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1741 Remove the DISKUS from your mouth. Hold your breath for about 10 seconds, or for as
1742 long as is comfortable. Breathe out slowly.

1743 The DISKUS delivers your dose of medicine as a very fine powder. Most patients can
1744 taste or feel the powder. Do not use another dose from the DISKUS if you do not feel or
1745 taste the medicine.

1746 Rinse your mouth with water after breathing-in the medicine. Spit the water out. Do not
1747 swallow.

1748 4. **Close the DISKUS when you are finished taking a dose so that the DISKUS will be**
1749 **ready for you to take your next dose.** Put your thumb on the thumbgrip and slide the
1750 thumbgrip back towards you as far as it will go (*see Figure 6*). The DISKUS will click
1751 shut. The lever will automatically return to its original position. The DISKUS is now
1752 ready for you to take your next scheduled dose, due in about 12 hours. (Repeat the steps 1
1753 to 4.)



Figure 6

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Remember:

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- Never breathe into the DISKUS.

1758

- Never take the DISKUS apart.

1759

- Always ready and use the DISKUS in a level, flat position.

1760

- Do not use the DISKUS with a spacer device.

1761

- After each dose, rinse your mouth with water and spit the water out. Do not swallow.

1762

- Never wash the mouthpiece or any part of the DISKUS. **Keep it dry.**

1763

- Always keep the DISKUS in a dry place.

1764

- Never take an extra dose, even if you did not taste or feel the medicine.

1765

Rx only

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GlaxoSmithKline

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GlaxoSmithKline

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Research Triangle Park, NC 27709

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Laboratories.

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1781 **This Medication Guide has been approved by the U.S. Food and Drug Administration.**