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1315 GlaxoSmithKline  
1316 Research Triangle Park, NC 27709

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1319  
1320 Month Year

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## MEDICATION GUIDE

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

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**ADVAIR<sup>®</sup> HFA 115/21 Inhalation Aerosol  
(fluticasone propionate 115 mcg and salmeterol 21 mcg)**

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**ADVAIR<sup>®</sup> HFA 230/21 Inhalation Aerosol  
(fluticasone propionate 230 mcg and salmeterol 21 mcg)**

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1333 Read the Medication Guide that comes with ADVAIR HFA before you start using it and each  
1334 time you get a refill. There may be new information. This Medication Guide does not take the  
1335 place of talking to your healthcare provider about your medical condition or treatment.

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

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#### **• ADVAIR HFA contains 2 medicines:**

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- **fluticasone propionate (the same medicine found in FLOVENT<sup>®</sup>)**, 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<sup>®</sup>)**, a long-acting beta<sub>2</sub>-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.

- 1349 • **In patients with asthma, LABA medicines, such as salmeterol (one of the medicines in**  
1350 **ADVAIR HFA), may increase the chance of death from asthma problems.** In a large  
1351 asthma study, more patients who used salmeterol died from asthma problems compared with  
1352 patients who did not use salmeterol. It is not known whether fluticasone propionate, the other  
1353 medicine in ADVAIR HFA, changes your chance of death from asthma problems seen with  
1354 salmeterol. Talk with your healthcare provider about this risk and the benefits of treating  
1355 your asthma with ADVAIR HFA.  
1356
- 1357 • **ADVAIR HFA does not relieve sudden symptoms. Always have a short-acting**  
1358 **beta<sub>2</sub>-agonist medicine with you to treat sudden symptoms. If you do not have an**  
1359 **inhaled, short-acting bronchodilator, contact your healthcare provider to have one**  
1360 **prescribed for you.**  
1361
- 1362 • **Do not stop using ADVAIR HFA unless told to do so by your healthcare provider**  
1363 **because your symptoms might get worse.**  
1364
- 1365 • **ADVAIR HFA should be used only if your healthcare provider decides that another**  
1366 **asthma-controller medicine alone does not control your asthma or that you need 2**  
1367 **asthma-controller medicines.**  
1368
- 1369 • **Call your healthcare provider if breathing problems worsen over time while using**  
1370 **ADVAIR HFA. You may need different treatment.**  
1371
- 1372 • **Get emergency medical care if:**
- 1373 • **breathing problems worsen quickly, and**
  - 1374 • **you use your short-acting beta<sub>2</sub>-agonist medicine, but it does not relieve your**  
1375 **breathing problems.**
- 1376

1377 **What is ADVAIR HFA?**

1378 ADVAIR HFA combines an inhaled corticosteroid medicine, fluticasone propionate (the same  
1379 medicine found in FLOVENT) and a long-acting beta<sub>2</sub>-agonist medicine, salmeterol (the same  
1380 medicine found in SEREVENT). ADVAIR HFA is used for asthma as follows:

1381

1382 ADVAIR HFA is used long term, twice a day to control symptoms of asthma, and prevent  
1383 symptoms such as wheezing in adolescents and adults 12 years of age and older.  
1384

1385 **ADVAIR HFA contains salmeterol (the same medicine found in SEREVENT). Because**  
1386 **LABA medicines, such as salmeterol, may increase the chance of death from asthma**  
1387 **problems, ADVAIR HFA is not for adults and children with asthma who:**

- 1388 • are well controlled with another asthma-controller medicine, such as a low to medium  
1389 dose of an inhaled corticosteroid medicine
- 1390 • only need short-acting beta<sub>2</sub>-agonist medicines once in awhile

1391

### 1392 **What should I tell my healthcare provider before using ADVAIR HFA?**

1393 **Tell your healthcare provider about all of your health conditions, including if you:**

- 1394 • **have heart problems**
- 1395 • **have high blood pressure**
- 1396 • **have seizures**
- 1397 • **have thyroid problems**
- 1398 • **have diabetes**
- 1399 • **have liver problems**
- 1400 • **have osteoporosis**
- 1401 • **have an immune system problem**
- 1402 • **are pregnant or planning to become pregnant.** It is not known if ADVAIR HFA may harm  
1403 your unborn baby.
- 1404 • **are breastfeeding.** It is not known if ADVAIR HFA passes into your milk and if it can harm  
1405 your baby.
- 1406 • **are allergic to ADVAIR HFA or any other medicines**
- 1407 • **are exposed to chickenpox or measles**

1408

1409 Tell your healthcare provider about all the medicines you take including prescription and  
1410 non-prescription medicines, vitamins, and herbal supplements. ADVAIR HFA and certain other  
1411 medicines may interact with each other. This may cause serious side effects. Especially, tell your  
1412 healthcare provider if you take ritonavir. The anti-HIV medicines NORVIR<sup>®</sup> (ritonavir capsules)  
1413 Soft Gelatin, NORVIR (ritonavir oral solution), and KALETRA<sup>®</sup> (lopinavir/ritonavir) Tablets  
1414 contain ritonavir.

1415

1416 Know the medicines you take. Keep a list and show it to your healthcare provider and pharmacist  
1417 each time you get a new medicine.

1418

### 1419 **How do I use ADVAIR HFA?**

1420 **See the step-by-step instructions for using ADVAIR HFA at the end of this Medication**  
1421 **Guide.** Do not use the ADVAIR HFA unless your healthcare provider has taught you and you  
1422 understand everything. Ask your healthcare provider or pharmacist if you have any questions.

1423

- 1424 • Use ADVAIR HFA exactly as prescribed. **Do not use ADVAIR HFA more often than**  
1425 **prescribed.** ADVAIR HFA comes in 3 strengths. Your healthcare provider will prescribe the  
1426 one that is best for your condition.

1427

- 1428 • The usual dosage of ADVAIR HFA is 2 inhalations twice a day (morning and evening). The  
1429 2 doses should be about 12 hours apart. Rinse your mouth with water after using ADVAIR  
1430 HFA.
- 1431
- 1432 • If you miss a dose of ADVAIR HFA, just skip that dose. Take your next dose at your usual  
1433 time. Do not take 2 doses at one time.
- 1434
- 1435 • **While you are using ADVAIR HFA twice a day, do not use other medicines that contain**  
1436 **a long-acting beta<sub>2</sub>-agonist or LABA for any reason. Other LABA-containing medicines**  
1437 **include ADVAIR DISKUS<sup>®</sup> (fluticasone propionate and salmeterol inhalation powder),**  
1438 **SEREVENT<sup>®</sup> DISKUS<sup>®</sup> (salmeterol xinafoate inhalation powder), FORADIL<sup>®</sup>**  
1439 **AEROLIZER<sup>®</sup> (formoterol fumarate inhalation powder), SYMBICORT<sup>®</sup> (budesonide**  
1440 **and formoterol fumarate dihydrate) Inhalation Aerosol, PERFORMIST<sup>™</sup>**  
1441 **(formoterol fumarate) Inhalation Solution, and BROVANA<sup>™</sup> (arformoterol tartrate)**  
1442 **Inhalation Solution.**
- 1443
- 1444 • Do not change or stop any of your medicines used to control or treat your breathing  
1445 problems. Your healthcare provider will adjust your medicines as needed.
- 1446
- 1447 • Make sure you always have a short-acting beta<sub>2</sub>-agonist medicine with you. Use your  
1448 short-acting beta<sub>2</sub>-agonist medicine if you have breathing problems between doses of  
1449 ADVAIR HFA.
- 1450
- 1451 • **Call your healthcare provider or get medical care right away if:**
- 1452 • your breathing problems worsen with ADVAIR HFA
- 1453 • you need to use your short-acting beta<sub>2</sub>-agonist medicine more often than usual
- 1454 • your short-acting beta<sub>2</sub>-agonist medicine does not work as well for you at relieving  
1455 symptoms
- 1456 • you need to use 4 or more inhalations of your short-acting beta<sub>2</sub>-agonist medicine for 2 or  
1457 more days in a row
- 1458 • you use 1 whole canister of your short-acting beta<sub>2</sub>-agonist medicine in 8 weeks' time
- 1459 • your peak flow meter results decrease. Your healthcare provider will tell you the numbers  
1460 that are right for you.
- 1461 • you have asthma and your symptoms do not improve after using ADVAIR HFA regularly  
1462 for 1 week
- 1463
- 1464 **What are the possible side effects with ADVAIR HFA?**
- 1465 • **ADVAIR HFA contains salmeterol (the same medicine found in SEREVENT). In**  
1466 **patients with asthma, LABA medicines, such as salmeterol, may increase the chance of**

1467 **death from asthma problems.** See “What is the most important information I should know  
1468 about ADVAIR HFA?”

1469

1470 **Other possible side effects with ADVAIR HFA include:**

1471 • **serious allergic reactions including rash; hives; swelling of the face, mouth, and tongue;**  
1472 **and breathing problems.** Call your healthcare provider or get emergency medical care if  
1473 you get any symptoms of a serious allergic reaction.

1474 • **increased blood pressure**

1475 • **a fast and irregular heartbeat**

1476 • **chest pain**

1477 • **headache**

1478 • **tremor**

1479 • **nervousness**

1480 • **immune system effects and a higher chance for infections**

1481 • **lower bone mineral density.** This may be a problem for people who already have a higher  
1482 chance for low bone density (osteoporosis).

1483 • **eye problems including glaucoma and cataracts.** You should have regular eye exams  
1484 while using ADVAIR HFA.

1485 • **slowed growth in children.** A child’s growth should be checked often.

1486 • **throat irritation**

1487

1488 Tell your healthcare provider about any side effect that bothers you or that does not go away.

1489

1490 These are not all the side effects with ADVAIR HFA. Ask your healthcare provider or  
1491 pharmacist for more information.

1492

1493 Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-  
1494 800-FDA-1088.

1495

1496 **How do I store ADVAIR HFA?**

1497 • **Store ADVAIR HFA at room temperature with the mouthpiece down.**

1498 • **Do not puncture the canister. Do not use or store ADVAIR HFA near heat or an open**  
1499 **flame. Never throw it into a fire or incinerator.**

1500 • **Keep ADVAIR HFA and all medicines out of the reach of children.**

1501

1502 **General Information about ADVAIR HFA**

1503 Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not  
1504 use ADVAIR HFA for a condition for which it was not prescribed. Do not give your ADVAIR  
1505 HFA to other people, even if they have the same condition. It may harm them.

1506 This Medication Guide summarizes the most important information about ADVAIR HFA. If you  
1507 would like more information, talk with your healthcare provider or pharmacist. You can ask your  
1508 healthcare provider or pharmacist for information about ADVAIR HFA that was written for  
1509 healthcare professionals. You can also contact the company that makes ADVAIR HFA (toll free)  
1510 at 1-888-825-5249 or at [www.advair.com](http://www.advair.com).

1511

1512

### **Instructions for Using Your ADVAIR HFA**

1513 Follow the instructions below for using your ADVAIR HFA.

1514 Take your ADVAIR HFA inhaler out of the moisture-protective foil pouch just before you use it  
1515 for the first time. Safely throw away the foil pouch and the drying packet that comes inside the  
1516 pouch.

1517 The inhaler should be at room temperature before you use it.

1518 **The purple actuator that comes with ADVAIR HFA should not be used with any other**  
1519 **product canisters. Actuators that come with other products should not be used with an**  
1520 **ADVAIR HFA canister.**

1521 **Prime the inhaler** before using it for the first time. To prime the inhaler, shake it well for  
1522 5 seconds. Then spray it 1 time into the air away from your face. Shake and spray the inhaler like  
1523 this 3 more times to finish priming it. **Avoid spraying in eyes.**

1524 If you have not used your inhaler in more than 4 weeks or if you have dropped it, shake it well  
1525 for 5 seconds and spray it 2 times into the air away from your face.

1526 **Shake the inhaler well** for 5 seconds just before each use.

1527 **1.** Take the cap off the mouthpiece (see Figure 1). The strap on the cap will stay attached to the  
1528 actuator.

1529 Look for foreign objects inside the inhaler before each use, especially if the strap is no longer  
1530 attached to the actuator or if the cap is not being used to cover the mouthpiece.

1531 Make sure the canister is fully and firmly inserted into the actuator.

1532 **Shake the inhaler well** for 5 seconds right before each use.

1533

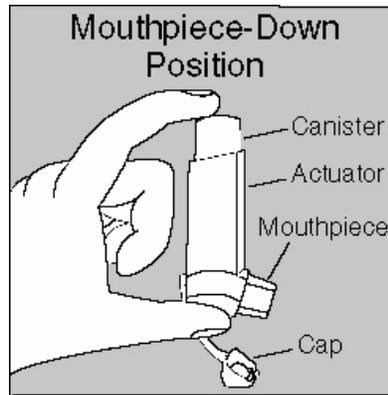


Figure 1

1534

1535

1536

1537 **2. Breathe out fully through your mouth, pushing as much air out of your lungs as you can.**

1538 Put the mouthpiece all the way into your mouth. Hold the inhaler with the mouthpiece down  
1539 (see Figure 1). Close your lips around it.

1540 **3. It is important to get the medicine in the spray into your lungs where it works. To do this, you**  
1541 **need to inhale the spray at the same time you take in a slow, deep breath.**

1542 So, just after starting to take in a slow, deep breath through your mouth, press down firmly on  
1543 the top of the metal canister (see Figure 2) and keep breathing in through your mouth.

1544 Take your finger off the canister after the spray comes out of the canister. Take the  
1545 mouthpiece out of your mouth after you have finished breathing in.

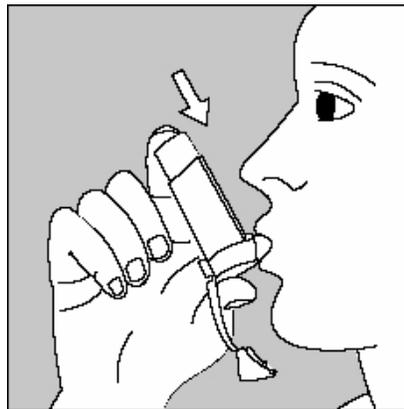


Figure 2

1546

1547

1548 **4. Hold your breath as long as you can, up to 10 seconds. Then breathe normally.**

1549 **5. Wait about 30 seconds and shake the inhaler again. Repeat steps 2 through 4.**

1550 **6. Put the cap back on the mouthpiece after each time you use the inhaler.**

1551 **7. After you finish taking this medicine, rinse your mouth with water. Spit out the water. Do not**  
1552 **swallow it.**

1553 8. Never put the canister in water to find out how much medicine is left in the canister (“float  
1554 test”).

1555 9. You should keep track of the number of inhalations used from your inhaler. **Then throw away**  
1556 **the inhaler after you have used 120 inhalations.** Even though the canister might not be empty  
1557 and will keep spraying, you might not get the right amount of medicine in each inhalation.  
1558 Before you get to 120 inhalations, ask your doctor if you need to refill your prescription.

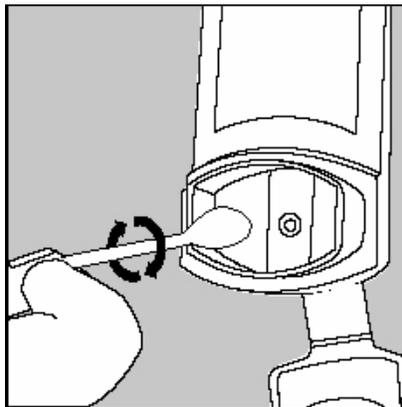
1559 **Do not** use after the expiration date, which is shown as “EXP” on the product label and box.

1560 **Cleaning your ADVAIR HFA Inhalation Aerosol:**

1561 Clean the inhaler at least once a week after your evening dose. Keeping the canister and plastic  
1562 actuator clean is important to prevent medicine buildup.

1563 Step 1. Take the cap off the mouthpiece. The strap on the cap will stay attached to the actuator.  
1564 Do not take the canister out of the plastic actuator.

1565 Step 2. Use a dry cotton swab to clean the small circular opening where the medicine sprays out  
1566 of the canister. Carefully twist the swab in a circular motion to take off any medicine (see Figure  
1567 3). Then wipe the inside of the mouthpiece with a clean tissue dampened with water. Let the  
1568 actuator air-dry overnight.



1569  
1570 Figure 3

1571 Step 3. Put the mouthpiece cover back on after the actuator has dried.

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1573 **Rx only**

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1576  **GlaxoSmithKline**

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1578 Research Triangle Park, NC 27709  
1579

1580 ADVAIR, ADVAIR DISKUS, FLOVENT, SEREVENT, and DISKUS are registered trademarks  
1581 of GlaxoSmithKline.

1582 The following are registered trademarks of their respective manufacturers: NORVIR and  
1583 KALETRA/Abbott Laboratories, FORADIL AEROLIZER/Novartis Pharmaceuticals  
1584 Corporation, SYMBICORT/AstraZeneca group of companies. The following are trademarks of  
1585 their respective manufacturers: PERFOROMIST/Dey, L.P.; BROVANA/Sepracor Inc.

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1588  
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1591 This Medication Guide has been approved by the U.S. Food and Drug Administration.  
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**PHARMACIST—DETACH HERE AND GIVE MEDICATION GUIDE TO PATIENT**

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1593

1594 **MEDICATION GUIDE**

1595  
1596 **ADVAIR<sup>®</sup> HFA [*ad' vair*] 45/21 Inhalation Aerosol**  
1597 **(fluticasone propionate 45 mcg and salmeterol 21 mcg)**

1598  
1599 **ADVAIR<sup>®</sup> HFA 115/21 Inhalation Aerosol**  
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1601  
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1606 time you get a refill. There may be new information. This Medication Guide does not take the  
1607 place of talking to your healthcare provider about your medical condition or treatment.

1608  
1609 **What is the most important information I should know about ADVAIR HFA?**

- 1610 • **ADVAIR HFA contains 2 medicines:**
- 1611 • **fluticasone propionate (the same medicine found in FLOVENT<sup>®</sup>),** an inhaled  
1612 corticosteroid medicine. Inhaled corticosteroids help to decrease inflammation in the  
1613 lungs. Inflammation in the lungs can lead to asthma symptoms.
  - 1614 • **salmeterol (the same medicine found in SEREVENT<sup>®</sup>),** a long-acting beta<sub>2</sub>-agonist  
1615 medicine or LABA. LABA medicines are used in patients with asthma. LABA medicines  
1616 help the muscles around the airways in your lungs stay relaxed to prevent symptoms,  
1617 such as wheezing and shortness of breath. These symptoms can happen when the muscles

1618 around the airways tighten. This makes it hard to breathe. In severe cases, wheezing can  
1619 stop your breathing and cause death if not treated right away.

1620

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1622 **ADVAIR HFA), may increase the chance of death from asthma problems.** In a large  
1623 asthma study, more patients who used salmeterol died from asthma problems compared with  
1624 patients who did not use salmeterol. It is not known whether fluticasone propionate, the other  
1625 medicine in ADVAIR HFA, changes your chance of death from asthma problems seen with  
1626 salmeterol. Talk with your healthcare provider about this risk and the benefits of treating  
1627 your asthma with ADVAIR HFA.

1628

1629 • **ADVAIR HFA does not relieve sudden symptoms. Always have a short-acting**  
1630 **beta<sub>2</sub>-agonist medicine with you to treat sudden symptoms. If you do not have an**  
1631 **inhaled, short-acting bronchodilator, contact your healthcare provider to have one**  
1632 **prescribed for you.**

1633

1634 • **Do not stop using ADVAIR HFA unless told to do so by your healthcare provider**  
1635 **because your symptoms might get worse.**

1636

1637 • **ADVAIR HFA should be used only if your healthcare provider decides that another**  
1638 **asthma-controller medicine alone does not control your asthma or that you need 2**  
1639 **asthma-controller medicines.**

1640

1641 • **Call your healthcare provider if breathing problems worsen over time while using**  
1642 **ADVAIR HFA. You may need different treatment.**

1643

1644 • **Get emergency medical care if:**

1645 • **breathing problems worsen quickly, and**

1646 • **you use your short-acting beta<sub>2</sub>-agonist medicine, but it does not relieve your**  
1647 **breathing problems.**

1648

1649 **What is ADVAIR HFA?**

1650 ADVAIR HFA combines an inhaled corticosteroid medicine, fluticasone propionate (the same  
1651 medicine found in FLOVENT) and a long-acting beta<sub>2</sub>-agonist medicine, salmeterol (the same  
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1655 symptoms such as wheezing in adolescents and adults 12 years of age and older.

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1658 **LABA medicines, such as salmeterol, may increase the chance of death from asthma**  
1659 **problems, ADVAIR HFA is not for adults and children with asthma who:**  
1660     • are well controlled with another asthma-controller medicine, such as a low to medium  
1661     dose of an inhaled corticosteroid medicine  
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1663

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- 1667 • **have high blood pressure**
- 1668 • **have seizures**
- 1669 • **have thyroid problems**
- 1670 • **have diabetes**
- 1671 • **have liver problems**
- 1672 • **have osteoporosis**
- 1673 • **have an immune system problem**
- 1674 • **are pregnant or planning to become pregnant.** It is not known if ADVAIR HFA may harm  
1675 your unborn baby.
- 1676 • **are breastfeeding.** It is not known if ADVAIR HFA passes into your milk and if it can harm  
1677 your baby.
- 1678 • **are allergic to ADVAIR HFA or any other medicines**
- 1679 • **are exposed to chickenpox or measles**

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1682 non-prescription medicines, vitamins, and herbal supplements. ADVAIR HFA and certain other  
1683 medicines may interact with each other. This may cause serious side effects. Especially, tell your  
1684 healthcare provider if you take ritonavir. The anti-HIV medicines NORVIR<sup>®</sup> (ritonavir capsules)  
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1693 **Guide.** Do not use the ADVAIR HFA unless your healthcare provider has taught you and you  
1694 understand everything. Ask your healthcare provider or pharmacist if you have any questions.  
1695

- 1696 • Use ADVAIR HFA exactly as prescribed. **Do not use ADVAIR HFA more often than**  
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 1698 one that is best for your condition.  
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- 1700 • The usual dosage of ADVAIR HFA is 2 inhalations twice a day (morning and evening). The  
 1701 2 doses should be about 12 hours apart. Rinse your mouth with water after using ADVAIR  
 1702 HFA.  
 1703
- 1704 • If you miss a dose of ADVAIR HFA, just skip that dose. Take your next dose at your usual  
 1705 time. Do not take 2 doses at one time.  
 1706
- 1707 • **While you are using ADVAIR HFA twice a day, do not use other medicines that contain**  
 1708 **a long-acting beta<sub>2</sub>-agonist or LABA for any reason. Other LABA-containing medicines**  
 1709 **include ADVAIR DISKUS<sup>®</sup> (fluticasone propionate and salmeterol inhalation powder), SEREVENT<sup>®</sup>**  
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 1713 **(formoterol fumarate) Inhalation Solution, and BROVANA<sup>™</sup> (arformoterol tartrate)**  
 1714 **Inhalation Solution.**  
 1715
- 1716 • Do not change or stop any of your medicines used to control or treat your breathing  
 1717 problems. Your healthcare provider will adjust your medicines as needed.  
 1718
- 1719 • Make sure you always have a short-acting beta<sub>2</sub>-agonist medicine with you. Use your  
 1720 short-acting beta<sub>2</sub>-agonist medicine if you have breathing problems between doses of  
 1721 ADVAIR HFA.  
 1722
- 1723 • **Call your healthcare provider or get medical care right away if:**  
 1724 • your breathing problems worsen with ADVAIR HFA  
 1725 • you need to use your short-acting beta<sub>2</sub>-agonist medicine more often than usual  
 1726 • your short-acting beta<sub>2</sub>-agonist medicine does not work as well for you at relieving  
 1727 symptoms  
 1728 • you need to use 4 or more inhalations of your short-acting beta<sub>2</sub>-agonist medicine for 2 or  
 1729 more days in a row  
 1730 • you use 1 whole canister of your short-acting beta<sub>2</sub>-agonist medicine in 8 weeks' time  
 1731 • your peak flow meter results decrease. Your healthcare provider will tell you the numbers  
 1732 that are right for you.  
 1733 • you have asthma and your symptoms do not improve after using ADVAIR HFA regularly  
 1734 for 1 week  
 1735

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1738 **patients with asthma, LABA medicines, such as salmeterol, may increase the chance of**  
1739 **death from asthma problems.** See “What is the most important information I should know  
1740 about ADVAIR HFA?”

1741  
1742 **Other possible side effects with ADVAIR HFA include:**  
1743 • **serious allergic reactions including rash; hives; swelling of the face, mouth, and tongue;**  
1744 **and breathing problems.** Call your healthcare provider or get emergency medical care if  
1745 you get any symptoms of a serious allergic reaction.  
1746 • **increased blood pressure**  
1747 • **a fast and irregular heartbeat**  
1748 • **chest pain**  
1749 • **headache**  
1750 • **tremor**  
1751 • **nervousness**  
1752 • **immune system effects and a higher chance for infections**  
1753 • **lower bone mineral density.** This may be a problem for people who already have a higher  
1754 chance for low bone density (osteoporosis).  
1755 • **eye problems including glaucoma and cataracts.** You should have regular eye exams  
1756 while using ADVAIR HFA.  
1757 • **slowed growth in children.** A child’s growth should be checked often.  
1758 • **throat irritation**

1759  
1760 Tell your healthcare provider about any side effect that bothers you or that does not go away.

1761  
1762 These are not all the side effects with ADVAIR HFA. Ask your healthcare provider or  
1763 pharmacist for more information.

1764  
1765 Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-  
1766 800-FDA-1088.

1767  
1768 **How do I store ADVAIR HFA?**

1769 • **Store ADVAIR HFA at room temperature with the mouthpiece down.**  
1770 • **Do not puncture the canister. Do not use or store ADVAIR HFA near heat or an open**  
1771 **flame. Never throw it into a fire or incinerator.**  
1772 • **Keep ADVAIR HFA and all medicines out of the reach of children.**

1773  
1774 **General Information about ADVAIR HFA**

1775 Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not  
1776 use ADVAIR HFA for a condition for which it was not prescribed. Do not give your ADVAIR  
1777 HFA to other people, even if they have the same condition. It may harm them.

1778 This Medication Guide summarizes the most important information about ADVAIR HFA. If you  
1779 would like more information, talk with your healthcare provider or pharmacist. You can ask your  
1780 healthcare provider or pharmacist for information about ADVAIR HFA that was written for  
1781 healthcare professionals. You can also contact the company that makes ADVAIR HFA (toll free)  
1782 at 1-888-825-5249 or at [www.advair.com](http://www.advair.com).

1783

1784

### Instructions for Using Your ADVAIR HFA

1785 Follow the instructions below for using your ADVAIR HFA.

1786 Take your ADVAIR HFA inhaler out of the moisture-protective foil pouch just before you use it  
1787 for the first time. Safely throw away the foil pouch and the drying packet that comes inside the  
1788 pouch.

1789 The inhaler should be at room temperature before you use it.

1790 **The purple actuator that comes with ADVAIR HFA should not be used with any other**  
1791 **product canisters. Actuators that come with other products should not be used with an**  
1792 **ADVAIR HFA canister.**

1793 **Prime the inhaler** before using it for the first time. To prime the inhaler, shake it well for  
1794 5 seconds. Then spray it 1 time into the air away from your face. Shake and spray the inhaler like  
1795 this 3 more times to finish priming it. **Avoid spraying in eyes.**

1796 If you have not used your inhaler in more than 4 weeks or if you have dropped it, shake it well  
1797 for 5 seconds and spray it 2 times into the air away from your face.

1798 **Shake the inhaler well** for 5 seconds just before each use.

1799 **1.** Take the cap off the mouthpiece (see Figure 1). The strap on the cap will stay attached to the  
1800 actuator.

1801 Look for foreign objects inside the inhaler before each use, especially if the strap is no longer  
1802 attached to the actuator or if the cap is not being used to cover the mouthpiece.

1803 Make sure the canister is fully and firmly inserted into the actuator.

1804 **Shake the inhaler well** for 5 seconds right before each use.

1805

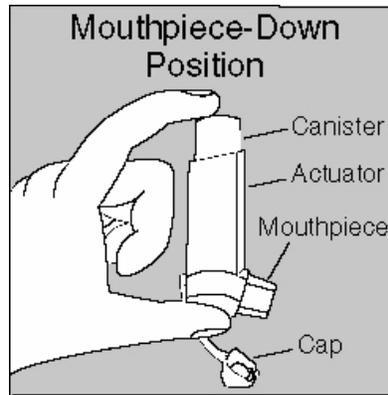


Figure 1

1806

1807

1808

1809 **2. Breathe out fully through your mouth, pushing as much air out of your lungs as you can.**

1810 Put the mouthpiece all the way into your mouth. Hold the inhaler with the mouthpiece down  
1811 (see Figure 1). Close your lips around it.

1812 **3. It is important to get the medicine in the spray into your lungs where it works. To do this, you**  
1813 **need to inhale the spray at the same time you take in a slow, deep breath.**

1814 So, just after starting to take in a slow, deep breath through your mouth, press down firmly on  
1815 the top of the metal canister (see Figure 2) and keep breathing in through your mouth.

1816 Take your finger off the canister after the spray comes out of the canister. Take the  
1817 mouthpiece out of your mouth after you have finished breathing in.

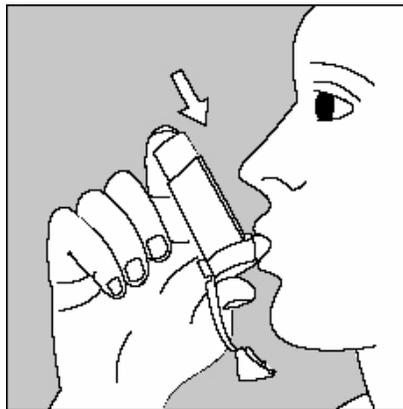


Figure 2

1818

1819

1820 **4. Hold your breath as long as you can, up to 10 seconds. Then breathe normally.**

1821 **5. Wait about 30 seconds and shake the inhaler again. Repeat steps 2 through 4.**

1822 **6. Put the cap back on the mouthpiece after each time you use the inhaler.**

1823 **7. After you finish taking this medicine, rinse your mouth with water. Spit out the water. Do not**  
1824 **swallow it.**

1825 8. Never put the canister in water to find out how much medicine is left in the canister (“float  
1826 test”).

1827 9. You should keep track of the number of inhalations used from your inhaler. **Then throw away**  
1828 **the inhaler after you have used 120 inhalations.** Even though the canister might not be empty  
1829 and will keep spraying, you might not get the right amount of medicine in each inhalation.  
1830 Before you get to 120 inhalations, ask your doctor if you need to refill your prescription.

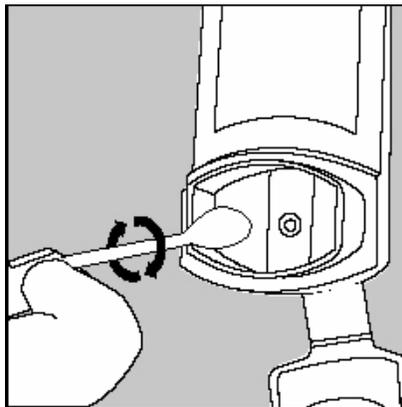
1831 **Do not** use after the expiration date, which is shown as “EXP” on the product label and box.

1832 **Cleaning your ADVAIR HFA Inhalation Aerosol:**

1833 Clean the inhaler at least once a week after your evening dose. Keeping the canister and plastic  
1834 actuator clean is important to prevent medicine buildup.

1835 Step 1. Take the cap off the mouthpiece. The strap on the cap will stay attached to the actuator.  
1836 Do not take the canister out of the plastic actuator.

1837 Step 2. Use a dry cotton swab to clean the small circular opening where the medicine sprays out  
1838 of the canister. Carefully twist the swab in a circular motion to take off any medicine (see Figure  
1839 3). Then wipe the inside of the mouthpiece with a clean tissue dampened with water. Let the  
1840 actuator air-dry overnight.



1841  
1842

Figure 3

1843 Step 3. Put the mouthpiece cover back on after the actuator has dried.

1844

1845 **Rx only**

1846

1847



1848

1849 GlaxoSmithKline

1850 Research Triangle Park, NC 27709

1851

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1858

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1860

1861 Month Year

1862

1863 This Medication Guide has been approved by the U.S. Food and Drug Administration.