

1328 plastic-coated, moisture-protective foil pouch with a desiccant that should be discarded when the  
1329 pouch is opened. Each canister is packaged with a Medication Guide leaflet.

1330 \*NDC 0173-0715-20 ADVAIR HFA 45/21 Inhalation Aerosol

1331 \*NDC 0173-0716-20 ADVAIR HFA 115/21 Inhalation Aerosol

1332 \*NDC 0173-0717-20 ADVAIR HFA 230/21 Inhalation Aerosol

1333 **The purple actuator supplied with ADVAIR HFA Inhalation Aerosol should not be used**  
1334 **with any other product canisters, and actuators from other products should not be used**  
1335 **with an ADVAIR HFA Inhalation Aerosol canister.**

1336 **The correct amount of medication in each actuation cannot be assured after the counter**  
1337 **reads 000, even though the canister is not completely empty and will continue to operate.**  
1338 **The inhaler should be discarded when the counter reads 000.**

1339 **Keep out of reach of children. Avoid spraying in eyes.**

1340 **Contents Under Pressure: Do not puncture. Do not use or store near heat or open flame.**  
1341 **Exposure to temperatures above 120°F may cause bursting. Never throw container into fire**  
1342 **or incinerator.**

1343 **Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). Store the inhaler with**  
1344 **the mouthpiece down. For best results, the inhaler should be at room temperature before**  
1345 **use. SHAKE WELL FOR 5 SECONDS BEFORE USING.**

1346 ADVAIR HFA Inhalation Aerosol does not contain chlorofluorocarbons (CFCs) as the  
1347 propellant.

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GlaxoSmithKline

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1351 GlaxoSmithKline

1352 Research Triangle Park, NC 27709

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1356 November 2008

ADH:3MG

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**PHARMACIST—DETACH HERE AND GIVE MEDICATION GUIDE TO PATIENT**

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1360

**MEDICATION GUIDE**

1361

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

1362

1363

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

1364

1365 **ADVAIR<sup>®</sup> HFA 230/21 Inhalation Aerosol**  
1366 **(fluticasone propionate 230 mcg and salmeterol 21 mcg)**  
1367

1368 Read the Medication Guide that comes with ADVAIR HFA Inhalation Aerosol before you start  
1369 using it and each time you get a refill. There may be new information. This Medication Guide  
1370 does not take the place of talking to your healthcare provider about your medical condition or  
1371 treatment.

1372  
1373 **What is the most important information I should know about ADVAIR HFA?**

1374 **ADVAIR HFA can cause serious side effects, including:**

- 1375 1. **People with asthma who take long-acting beta<sub>2</sub>-adrenergic agonist (LABA) medicines,**  
1376 **such as salmeterol (one of the medicines in ADVAIR HFA), have an increased risk of**  
1377 **death from asthma problems.** It is not known whether fluticasone propionate, the other  
1378 medicine in ADVAIR HFA, reduces the risk of death from asthma problems seen with  
1379 salmeterol.
- 1380 • **Call your healthcare provider if breathing problems worsen over time while using**  
1381 **ADVAIR HFA.** You may need different treatment.
  - 1382 • **Get emergency medical care if:**
    - 1383 • breathing problems worsen quickly and
    - 1384 • you use your rescue inhaler medicine, but it does not relieve your breathing problems.
- 1385 2. ADVAIR HFA should be used only if your healthcare provider decides that your asthma is  
1386 not well controlled with a long-term asthma-control medicine, such as inhaled  
1387 corticosteroids.
- 1388 3. When your asthma is well controlled, your healthcare provider may tell you to stop taking  
1389 ADVAIR HFA. Your healthcare provider will decide if you can stop ADVAIR HFA without  
1390 loss of asthma control. You healthcare provider may prescribe a different long-term asthma-  
1391 control medicine for you, such as an inhaled corticosteroid.
- 1392 4. Children and adolescents who take LABA medicines may have an increased risk of being  
1393 hospitalized for asthma problems.

1394  
1395 **What is ADVAIR HFA?**

- 1396 • ADVAIR HFA combines an inhaled corticosteroid medicine, fluticasone propionate (the  
1397 same medicine found in FLOVENT<sup>®</sup>), and a LABA medicine, salmeterol (the same medicine  
1398 found in SEREVENT<sup>®</sup>).
- 1399 • Inhaled corticosteroids help to decrease inflammation in the lungs. Inflammation in the  
1400 lungs can lead to asthma symptoms.

1401 • LABA medicines are used in people with asthma and chronic obstructive pulmonary  
1402 disease (COPD). LABA medicines help the muscles around the airways in your lungs  
1403 stay relaxed to prevent symptoms, such as wheezing and shortness of breath. These  
1404 symptoms can happen when the muscles around the airways tighten. This makes it hard  
1405 to breathe. In severe cases, wheezing can stop your breathing and cause death if not  
1406 treated right away.

1407 • ADVAIR HFA is used to control symptoms of asthma and to prevent symptoms such as  
1408 wheezing in adults and children aged 12 years and older.

1409 • ADVAIR HFA contains salmeterol (the same medicine found in SEREVENT). LABA  
1410 medicines, such as salmeterol, increase the risk of death from asthma problems.

1411 ADVAIR HFA is not for adults and children with asthma who:

1412 • are well controlled with an asthma-control medicine, such as a low to medium dose of an  
1413 inhaled corticosteroid medicine

1414

#### 1415 **Who should not use ADVAIR HFA?**

1416 Do not use ADVAIR HFA:

1417 • to treat sudden, severe symptoms of asthma and  
1418 • if you are allergic to any of the ingredients in ADVAIR HFA. See the end of this Medication  
1419 Guide for a list of ingredients in ADVAIR HFA.

1420

#### 1421 **What should I tell my healthcare provider before using ADVAIR HFA?**

1422 **Tell your healthcare provider about all of your health conditions, including if you:**

1423 • **have heart problems**

1424 • **have high blood pressure**

1425 • **have seizures**

1426 • **have thyroid problems**

1427 • **have diabetes**

1428 • **have liver problems**

1429 • **have osteoporosis**

1430 • **have an immune system problem**

1431 • **are pregnant or planning to become pregnant.** It is not known if ADVAIR HFA may harm  
1432 your unborn baby.

1433 • **are breastfeeding.** It is not known if ADVAIR HFA passes into your milk and if it can harm  
1434 your baby.

1435 • **are allergic to ADVAIR HFA or any other medicines**

1436 • **are exposed to chickenpox or measles**

1437 Tell your healthcare provider about all the medicines you take including prescription and  
1438 non-prescription medicines, vitamins, and herbal supplements. ADVAIR HFA and certain other  
1439 medicines may interact with each other. This may cause serious side effects. Especially, tell your  
1440 healthcare provider if you take ritonavir. The anti-HIV medicines NORVIR<sup>®</sup> (ritonavir capsules)  
1441 Soft Gelatin, NORVIR (ritonavir oral solution), and KALETRA<sup>®</sup> (lopinavir/ritonavir) Tablets  
1442 contain ritonavir.

1443 Know the medicines you take. Keep a list and show it to your healthcare provider and pharmacist  
1444 each time you get a new medicine.

1445

#### 1446 **How do I use ADVAIR HFA?**

1447 **See the step-by-step instructions for using ADVAIR HFA at the end of this Medication**

1448 **Guide.** Do not use ADVAIR HFA unless your healthcare provider has taught you and you  
1449 understand everything. Ask your healthcare provider or pharmacist if you have any questions.

- 1450 • Use ADVAIR HFA exactly as prescribed. **Do not use ADVAIR HFA more often than**  
1451 **prescribed.** ADVAIR HFA comes in 3 strengths. Your healthcare provider has prescribed  
1452 the one that is best for your condition.
- 1453 • The usual dosage of ADVAIR HFA is 2 inhalations 2 times each day (morning and evening).  
1454 The 2 doses should be about 12 hours apart. Rinse your mouth with water after using  
1455 ADVAIR HFA.
- 1456 • If you miss a dose of ADVAIR HFA, just skip that dose. Take your next dose at your usual  
1457 time. Do not take 2 doses at one time.
- 1458 • **While you are using ADVAIR HFA 2 times each day, do not use other medicines that**  
1459 **contain a LABA for any reason.** Ask your healthcare provider or pharmacist if any of your  
1460 other medicines are LABA medicines.
- 1461 • Do not stop using ADVAIR HFA or other asthma medicines unless told to do so by your  
1462 healthcare provider because your symptoms might get worse. Your healthcare provider will  
1463 change your medicines as needed.
- 1464 • ADVAIR HFA does not relieve sudden symptoms. Always have a rescue inhaler medicine  
1465 with you to treat sudden symptoms. If you do not have an inhaled, short-acting  
1466 bronchodilator, call your healthcare provider to have one prescribed for you.
- 1467 • Call your healthcare provider or get medical care right away if:
  - 1468 • your breathing problems worsen with ADVAIR HFA
  - 1469 • you need to use your rescue inhaler medicine more often than usual
  - 1470 • your rescue inhaler medicine does not work as well for you at relieving symptoms
  - 1471 • you need to use 4 or more inhalations of your rescue inhaler medicine for 2 or more days  
1472 in a row
  - 1473 • you use 1 whole canister of your rescue inhaler medicine in 8 weeks' time

- 1474 • your peak flow meter results decrease. Your healthcare provider will tell you the numbers  
1475 that are right for you.
- 1476 • you have asthma and your symptoms do not improve after using ADVAIR HFA regularly  
1477 for 1 week

1478

1479 **What are the possible side effects with ADVAIR HFA?**

1480 **ADVAIR HFA can cause serious side effects, including:**

1481 • **See “What is the most important information I should know about ADVAIR HFA?”**

1482 • **serious allergic reactions.** Call your healthcare provider or get emergency medical care if  
1483 you get any of the following symptoms of a serious allergic reaction:

- 1484 • rash
- 1485 • hives
- 1486 • swelling of the face, mouth, and tongue
- 1487 • breathing problems

1488 • **sudden breathing problems immediately after inhaling your medicine**

1489 • **effects on heart**

- 1490 • increased blood pressure
- 1491 • a fast and irregular heartbeat
- 1492 • chest pain

1493 • **effects on nervous system**

- 1494 • tremor
- 1495 • nervousness

1496 • **reduced adrenal function (may result in loss of energy)**

1497 • **changes in blood (sugar, potassium, certain types of white blood cells)**

1498 • **weakened immune system and a higher chance of infections**

1499 • **lower bone mineral density.** This may be a problem for people who already have a higher  
1500 chance of low bone density (osteoporosis).

1501 • **eye problems including glaucoma and cataracts.** You should have regular eye exams  
1502 while using ADVAIR HFA.

1503 • **slowed growth in children.** A child’s growth should be checked often.

1504 • **throat tightness**

1505 • **pneumonia.** ADVAIR HFA contains the same medicine found in ADVAIR DISKUS®.  
1506 ADVAIR DISKUS is used to treat people with asthma and people with chronic obstructive  
1507 pulmonary disease (COPD). People with COPD have a higher chance of getting pneumonia.  
1508 ADVAIR DISKUS may increase the chance of getting pneumonia. ADVAIR HFA has not

1509 been studied in people with COPD. Call your healthcare provider if you notice any of the  
1510 following symptoms:

- 1511 • increase in mucus (sputum) production
- 1512 • change in mucus color
- 1513 • fever
- 1514 • chills
- 1515 • increased cough
- 1516 • increased breathing problems

1517 **Common side effects of ADVAIR HFA include:**

- 1518 • upper respiratory tract infection
- 1519 • headache
- 1520 • throat irritation
- 1521 • musculoskeletal pain
- 1522 • nausea and vomiting

1523 Tell your healthcare provider about any side effect that bothers you or that does not go away.

1524 These are not all the side effects with ADVAIR HFA. Ask your healthcare provider or  
1525 pharmacist for more information.

1526 Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-  
1527 800-FDA-1088.

1528

1529 **How do I store ADVAIR HFA?**

- 1530 • Store at room temperature with the mouthpiece down.
- 1531 • **Contents Under Pressure:** Do not puncture. Do not use or store near heat or open flame.  
1532 Exposure to temperatures above 120°F may cause bursting.
- 1533 • Do not throw into fire or an incinerator.
- 1534 • Keep ADVAIR HFA and all medicines out of the reach of children.

1535

1536 **General Information about ADVAIR HFA**

1537 Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not  
1538 use ADVAIR HFA for a condition for which it was not prescribed. Do not give your ADVAIR  
1539 HFA to other people, even if they have the same condition that you have. It may harm them.

1540 This Medication Guide summarizes the most important information about ADVAIR HFA. If you  
1541 would like more information, talk with your healthcare provider or pharmacist. You can ask your  
1542 healthcare provider or pharmacist for information about ADVAIR HFA that was written for  
1543 healthcare professionals. You can also contact the company that makes ADVAIR HFA (toll free)  
1544 at 1-888-825-5249 or at [www.advail.com](http://www.advail.com).

1545

1546 **What are the ingredients in ADVAIR HFA?**

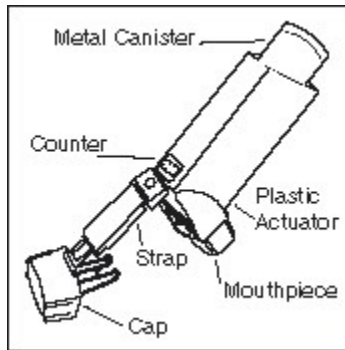
1547 Active ingredients: fluticasone propionate, salmeterol xinafoate

1548 Inactive ingredient: propellant HFA-134a

1549

1550 **How to use your ADVAIR HFA**

1551 **The parts of your ADVAIR HFA:**



1552 **Figure 1**

1555 There are 2 main parts to your ADVAIR HFA inhaler—  
1556 the metal canister that holds the medicine and the purple  
1557 plastic actuator that sprays the medicine from the canister  
1558 (see Figure 1).

1559 The inhaler also has a cap that covers the mouthpiece of  
1560 the actuator. The strap on the cap will stay attached to the  
1561 actuator.

1562 **Do not use the actuator with a canister of medicine**  
1563 **from any other inhaler. Do not use an ADVAIR HFA**  
1564 **canister with an actuator from any other inhaler.**

1565 The canister has a counter to show how many sprays of medicine you have left. The number  
1566 shows through a window in the back of the actuator.

1567 The counter starts at 124, or at 064 if you have a sample or institutional canister. The number  
1568 will count down by 1 each time you spray the inhaler. The counter will stop counting at 000.

1569 **Never try to change the numbers or take the counter off the metal canister.** The counter  
1570 cannot be reset, and it is permanently attached to the canister.

1571 **Before using your ADVAIR HFA:**

1572 Take the inhaler out of the foil pouch. Safely throw away the foil pouch and the drying packet  
1573 that comes inside the pouch. The counter should read 124, or 064 if you have a sample or  
1574 institutional canister.

1575 The inhaler should be at room temperature before you use it.

1576 Check each time to make sure the canister fits firmly in the plastic actuator. Also look into the  
1577 mouthpiece to make sure there are no foreign objects there, especially if the strap is no longer  
1578 attached to the actuator or if the cap is not being used to cover the mouthpiece.

1579 **Priming your ADVAIR HFA:**

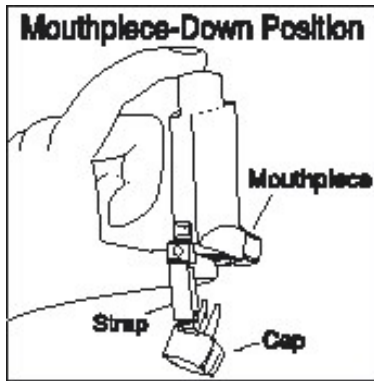
1580 Before you use ADVAIR HFA for the first time, you must prime the inhaler so that you will  
1581 get the right amount of medicine when you use it. To prime the inhaler, take the cap off the  
1582 mouthpiece and shake the inhaler well for 5 seconds. Then spray it 1 time into the air away from  
1583 your face. Shake and spray the inhaler like this 3 more times to finish priming it. **Avoid**  
1584 **spraying in eyes.** The counter should now read 120, or 060 if you have a sample or institutional  
1585 canister.

1586 You must prime your inhaler again if you have not used it in more than 4 weeks or if you have  
1587 dropped it. Take the cap off the mouthpiece, shake the inhaler well for 5 seconds, and spray it

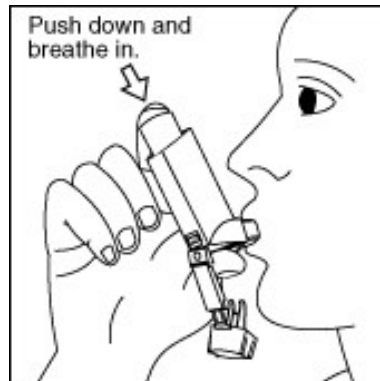
1588 into the air away from your face. Shake and spray the inhaler like this 1 more time to finish  
1589 priming it.

1590 **Instructions for taking a dose from your ADVAIR HFA:**

1591 Read through the 7 steps below before using ADVAIR HFA. If you have any questions, ask  
1592 your doctor or pharmacist.



1593  
1594 **Figure 2**



1596  
1597 **Figure 3**

- 1598 1. Take the cap off the mouthpiece of the actuator. **Shake the inhaler well** for 5 seconds before  
1599 each spray.
- 1600 2. Hold the inhaler with the mouthpiece down (see Figure 2). **Breathe out through your mouth**  
1601 and push as much air from your lungs as you can. Put the mouthpiece in your mouth and close  
1602 your lips around it.
- 1603 3. **Push the top of the canister all the way down while you breathe in deeply and slowly**  
1604 **through your mouth** (see Figure 3). Right after the spray comes out, take your finger off the  
1605 canister. After you have breathed in all the way, take the inhaler out of your mouth and close  
1606 your mouth.
- 1607 4. **Hold your breath as long as you can**, up to 10 seconds, then breathe normally.
- 1608 5. Wait about 30 seconds and **shake** the inhaler again for 5 seconds. Repeat steps 2 through 4.
- 1609 6. After you finish taking this medicine, rinse your mouth with water. Spit out the water. Do not  
1610 swallow it.
- 1611 7. Put the cap back on the mouthpiece after every time you use the inhaler, and make sure it  
1612 snaps firmly into place.

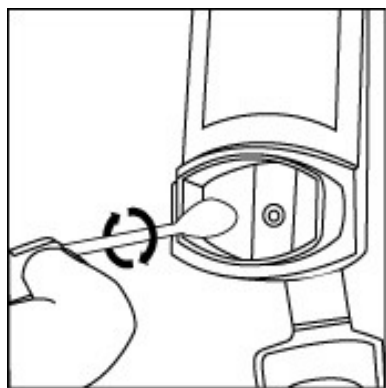
1613 **When to replace your ADVAIR HFA:**

- 1614 • **When the counter reads 020**, you should refill your prescription or ask your doctor if you  
1615 need another prescription for ADVAIR HFA.
- 1616 • **Throw the inhaler away** when the counter reads 000. You should not keep using the inhaler  
1617 when the counter reads 000 because you will not receive the right amount of medicine.
- 1618 • **Do not use the inhaler** after the expiration date, which is on the packaging it comes in.



1619 **How to clean your ADVAIR HFA:**

1620 Clean the inhaler at least once a week after your evening dose. It is important to keep the  
1621 canister and plastic actuator clean so the medicine will not build-up and block the spray.



1622 **Figure 4**

- 1625 1. Take the cap off the mouthpiece. The strap on the cap  
1626 will stay attached to the actuator. Do not take the canister  
1627 out of the plastic actuator.
- 1628 2. Use a dry cotton swab to clean the small circular  
1629 opening where the medicine sprays out of the canister.  
1630 Carefully twist the swab in a circular motion to take off  
1631 any medicine (see Figure 4).
- 1632 3. Wipe the inside of the mouthpiece with a clean tissue  
1633 dampened with water. Let the actuator air-dry overnight.
- 1634 4. Put the cap back on the mouthpiece after the actuator has  
1635 dried.

1636  
1637 **This Medication Guide has been approved by the U.S. Food and Drug Administration.**

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1640 GlaxoSmithKline.

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1642 GlaxoSmithKline. The makers of these brands are not affiliated with and do not endorse  
1643 GlaxoSmithKline or its products.

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