

ALVESCO® (ciclesonide) Inhalation Aerosol 80 mcg
ALVESCO® (ciclesonide) Inhalation Aerosol 160 mcg
For Oral Inhalation Only

Patient Instructions for Use

Read this leaflet carefully before starting to take this medicine. This leaflet provides a summary of information about ALVESCO, and does not contain the complete information about this medication. If you have any questions about ALVESCO, ask your health care provider or pharmacist.

What is ALVESCO?

Your health care provider has prescribed ALVESCO for the long-term treatment of your asthma. The medicine is available in 2 different strengths, and your health care provider has chosen the one most suitable for you.

ALVESCO contains ciclesonide, a man-made corticosteroid. Corticosteroids are natural anti-inflammatory substances found in the body. ALVESCO is used as maintenance treatment that helps prevent and control asthma symptoms because ALVESCO reduces airway inflammation.

When inhaled regularly, as prescribed by your health care provider, ALVESCO will help to prevent and control symptoms of asthma.

ALVESCO is not a bronchodilator. You should not use ALVESCO when you are having sudden symptoms of shortness of breath. Use an inhaled short-acting bronchodilator such as albuterol to relieve sudden symptoms of shortness of breath.

What Should I Tell My Health Care Provider Before Taking ALVESCO?

Tell your health care provider:

- If you are pregnant or plan to become pregnant.
- If you are breast-feeding.
- About any past or present medical problems or allergies.
- About all medicines that you are taking or plan to take, including those you can get without a prescription.
- If you have or had TB.
- If you are exposed to anyone with chicken pox or measles, or about any other infections you had before or while using ALVESCO.

Important Points to Remember About Using ALVESCO

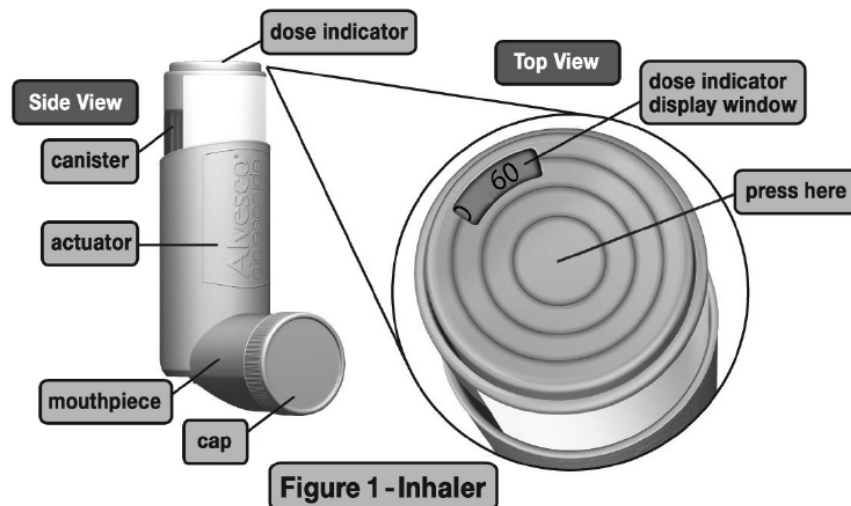
- **ALVESCO IS NOT A BRONCHODILATOR AND IS NOT INTENDED TO PROVIDE RAPID RELIEF OF BREATHING DIFFICULTIES DURING AN ASTHMA ATTACK.**
- ALVESCO must be taken at regular intervals as recommended by your health care provider, and not as an emergency measure. Your health care provider may prescribe another medication (such as bronchodilator) for rapid relief if an asthma attack occurs. Please contact your health care provider if:
 - an asthma attack does not respond to the other medication.
 - you require more of the other medication than usual.
- It is important that you inhale each dose of ALVESCO as your health care provider has advised. **DO NOT** inhale more doses or use your ALVESCO more often than your health care provider advises.
- It may take four weeks or longer to feel the full benefit of this medicine. Contact your health care provider if your symptoms do not improve in that time frame or if your condition worsens at any point during treatment.
- **It is important that you continue to use ALVESCO regularly. Do not stop treatment even if you are feeling better** unless told to do so by your health care provider.
- If you miss one dose of your medicine wait and take your regularly scheduled next dose.
- If you also use another medicine by inhalation, you should consult your health care provider for instructions on when to use it in relation to using ALVESCO.
- Use your ALVESCO Inhalation Aerosol canister with ALVESCO Inhalation Aerosol actuator only.
- Do not use the ALVESCO actuator with any other inhalation medications.

How to Use ALVESCO

Follow the instructions below. If you have any questions, ask your health care provider or pharmacist.

Your ALVESCO inhaler is fitted with a dose indicator which shows you how much of your medicine is left during use. The dose indicator display will move every tenth time you take a puff. The dose indicator display window will turn red when there are only 20 puffs remaining. This means that you need to replace your inhaler soon. The canister should be discarded when the dose indicator display window shows zero.

While your inhaler is fitted with a dose indicator to help determine the approximate number of puffs remaining, you should keep track of the number of puffs used from each canister of ALVESCO (see Step 8 below).



On the first use of your ALVESCO inhaler, as with all aerosol medicine, you should “test spray” the inhaler. To do this, remove the plastic cap and check the dose indicator on top of the inhaler to ensure that the dose indicator display window pointer is before the “60” inhalation mark before the first use. The “test spray” should also be done if the inhaler has not been used for more than 10 days. Spray 3 times into the air, away from the face by pressing firmly onto the center (not ‘off center’) of the dose indicator button, indicated by the middle of the three concentric rings on the button (see Figure 1). Be sure the canister is firmly seated in the plastic mouthpiece adapter before each use and that you press the inhaler slowly and firmly until it moves no further in the adapter for each spray.

You do not need to shake your ALVESCO inhaler before use. Check the dose indicator before the first use after the “test spray.” Check that the dose indicator display window shows that there are 60 inhalations left in the inhaler. If this is not the case, please return it to the pharmacy.

Steps for Inhalation:

1. Remove the plastic cap.
2. Breathe out as fully as you comfortably can. Hold the inhaler as shown in Figure 2. Close your lips around the mouthpiece, keeping your tongue below it.



3. While breathing in deeply and slowly, press down on the center (not 'off center') of the dose indicator with your finger. Fully depress the canister until it stops moving in the adapter while delivering your dose. When you have finished breathing in, hold your breath for about 10 seconds, or for as long as is comfortable. Note: It is normal to hear a soft click from the indicator as it counts down during use.
4. Take your finger completely off the center of the dose indicator and remove the inhaler from your mouth. Breathe out gently.
5. After use, always replace the cap to keep the mouthpiece clean. Note: The mouthpiece of your inhaler should be cleaned weekly with a clean, dry tissue or cloth.
6. After you finish taking your dose, rinse your mouth with water and spit it out. Do not swallow.
7. **DO NOT WASH OR PUT ANY PART OF YOUR INHALER IN WATER.**
8. **DISCARD THE ALVESCO INHALER WHEN THE DOSE INDICATOR DISPLAY WINDOW SHOWS ZERO.** The correct amount of medicine in each inhalation cannot be assured after this point. Note: If the inhaler is dropped, do not rely on the dose indicator. It is recommended to keep track of the number of inhalations taken from your inhaler based on your records.

POSSIBLE SIDE EFFECTS WITH ALVESCO

Serious Side Effects may include:

- **Adrenal Insufficiency (your adrenal gland can not produce enough steroids since you were on oral steroid medicine).** If you took steroids by mouth and are having them decreased (tapered) or you are being switched to ALVESCO, you should be followed closely by your doctor. Death can occur. Tell your doctor right away about any symptoms such as feeling tired or exhausted, weakness, nausea, vomiting or symptoms of low blood pressure (such as dizziness or faintness). If you are under stress, such as with surgery, after surgery or trauma, you may need steroids by mouth again.
- **Decreased bone mass (bone mineral density).** Patients who use inhaled steroid medicines for a long time may have an increased risk of decreased bone mass which can affect bone strength. Talk with your healthcare provider about any questions about bone health.
- **Possible increased risk of infection due to a weakened immune system with using steroid medicines.**
- **Bronchospasm (spasm of the breathing tubes)** can occur, with wheezing right after a dose of the medicine. **Stop using ALVESCO and use an inhaled short-acting bronchodilator right away, such as albuterol.** Tell your healthcare provider right away so that a new maintenance medicine can be prescribed for your or your child's asthma.

The most common side effects with ALVESCO include: headache, nasopharyngitis, sinusitis, pharyngolaryngeal pain, upper respiratory infection, arthralgia, nasal congestion, pain in extremity and back pain.

Tell your doctor about any side effects that bother you or do not go away. These are not all of the possible side effects with ALVESCO. For more information, ask your doctor or pharmacist.

How to Store ALVESCO

For best results, store and use ALVESCO at room temperature.

Keep out of reach of children.

CONTENTS UNDER PRESSURE. Do not puncture. Do not use or store near heat or open flame. Exposure to temperature above 120°F (49°C) may cause bursting. Never throw canister into fire or incinerator.

DO NOT USE after the expiration date, shown as "Exp" on the package label or box.

Further Information

REMEMBER: This medicine has been prescribed for you by your health care provider. DO NOT give this medicine to anyone else.

This leaflet does not contain the complete information about your medication. *If you have any questions, or are not sure about something, then you should ask your health care provider or pharmacist.*

Because you may want to refer to this leaflet again, you may want to keep it until you have finished your medicine.

Manufactured for:
Sepracor Inc.
Marlborough, MA 01752 USA
Made in the United Kingdom

ALVESCO is a registered trademark of Nycomed GmbH and is used with permission.

US Patent Nos. 5,482,934; 6,264,923

©2007 Nycomed

May 2008