

Patient Information

ALVESCO® [æl-ˈves-koʊ]

(ciclesonide)

Inhalation Aerosol

Note: For Oral Inhalation Only

Do not use your ALVESCO Inhalation Aerosol near heat or an open flame.

Read this Patient Information leaflet before you start using ALVESCO Inhalation Aerosol and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment. If you have any questions about ALVESCO Inhalation Aerosol, ask your healthcare provider or pharmacist.

What is ALVESCO Inhalation Aerosol?

ALVESCO Inhalation Aerosol is a prescription medicine used for the control and prevention of asthma in adults and children 12 years of age and older.

ALVESCO Inhalation Aerosol contains ciclesonide, which is a man-made (synthetic) corticosteroid. Corticosteroids are natural substances found in the body and reduce inflammation. When you inhale ALVESCO Inhalation Aerosol it may help to control and prevent your symptoms of asthma by reducing your airway inflammation.

ALVESCO Inhalation Aerosol is not for the relief of acute bronchospasm. ALVESCO Inhalation Aerosol is not a bronchodilator and does not treat sudden symptoms of an asthma attack such as wheezing, cough, shortness of breath, and chest pain or tightness. **Always have a fast-acting bronchodilator medicine (rescue inhaler) with you to treat sudden symptoms.**

It is not known if ALVESCO Inhalation Aerosol is safe and effective in children 11 years of age and younger.

Who should not use ALVESCO Inhalation Aerosol?

Do not use ALVESCO Inhalation Aerosol:

- to treat status asthmaticus or other sudden symptoms of asthma. ALVESCO Inhalation Aerosol is not a rescue inhaler and should not be used to give you fast relief from your asthma attack. **Always use a rescue inhaler such as albuterol, during a sudden asthma attack.**
- if you are allergic to ciclesonide or any of the ingredients in ALVESCO Inhalation Aerosol. See the end of this Patient Information leaflet for a complete list of ingredients in ALVESCO Inhalation Aerosol.

What should I tell my healthcare provider before using ALVESCO Inhalation Aerosol?

Before you use ALVESCO Inhalation Aerosol tell your healthcare provider if you:

- have or have had eye problems such as increased ocular pressure, glaucoma, or cataracts.
- have any infections including tuberculosis or ocular herpes simplex.
- have not had or been vaccinated for chicken pox or measles.
- are pregnant or plan to become pregnant. It is not known if ALVESCO Inhalation Aerosol will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.

- are breastfeeding or plan to breastfeed. It is not known if ALVESCO Inhalation Aerosol passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you are using ALVESCO Inhalation Aerosol.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use ALVESCO Inhalation Aerosol?

- Read the Instructions for Use at the end of this leaflet for specific information about the right way to use ALVESCO Inhalation Aerosol.
- Use ALVESCO Inhalation Aerosol exactly as your healthcare provider tells you to use it. Do not take more of your medicine, or take it more often than your healthcare provider tells you.
- You must use ALVESCO Inhalation Aerosol regularly. It may take 4 weeks or longer after you start using ALVESCO Inhalation Aerosol for your asthma symptoms to get better. **Do not stop using ALVESCO Inhalation Aerosol even if you are feeling better, unless your healthcare provider tells you to.**
- If your symptoms do not improve or get worse, call your healthcare provider.
- Your healthcare provider may prescribe a rescue inhaler for emergency relief of sudden asthma attacks. Call your healthcare provider if you have:
 - an asthma attack that does not respond to your rescue inhaler **or**
 - you need more of your rescue inhaler than usual.
- If you use another inhaled medicine, ask your healthcare provider for instructions on how to use it while you use ALVESCO Inhalation Aerosol.

What are the possible side effects of ALVESCO Inhalation Aerosol?

ALVESCO Inhalation Aerosol may cause serious side effects, including:

- **Thrush (Candida), a fungal infection of your nose, mouth, or throat.** Tell your healthcare provider if you have discomfort or pain in your throat, have hoarseness in your voice or have any redness or white colored patches in your mouth or throat. Rinse your mouth after you use your ALVESCO Inhalation Aerosol.
- **Immune system problems that may increase your risk of infections.** You are more likely to get infections if you take medicines that may weaken your body's ability to fight infections. Avoid contact with people who have contagious diseases such as chicken pox or measles while you use ALVESCO Inhalation Aerosol. Symptoms of an infection may include:
 - fever
 - pain
 - aches
 - chills
 - feeling tired
 - nausea
 - vomiting
- **Adrenal insufficiency.** Adrenal insufficiency is a condition in which the adrenal glands do not make enough steroid hormones. Your healthcare provider will follow you closely if you take steroids by mouth and are having them decreased (tapered) or you are being switched to ALVESCO Inhalation Aerosol. People have died while steroids are being decreased and when people have been switched from steroids by mouth to inhaled steroids like ALVESCO. If you are under stress, such as with surgery, after surgery or trauma, you may need steroids by

mouth again.

Call your healthcare provider right away if you have the following symptoms of adrenal insufficiency:

- tiredness
- weakness
- dizziness
- nausea that does not go away
- vomiting that does not go away
- **Decreased bone mass (bone mineral density).** People who use inhaled steroid medicines for a long time may have an increased risk of decreased bone mass which can affect bone strength. Talk to your healthcare provider about any concerns you may have about bone health.
- **Slowed or delayed growth in children.** A child's growth should be checked regularly while using ALVESCO Inhalation Aerosol.
- **Eye problems such as glaucoma and cataracts.** If you have a history of glaucoma or cataracts or have a family history of eye problems, you should have regular eye exams while you use ALVESCO Inhalation Aerosol.
- **Increased wheezing (bronchospasm)** can happen right away after using ALVESCO Inhalation Aerosol. **Stop using ALVESCO Inhalation Aerosol and use an inhaled fast-acting bronchodilator (rescue inhaler) right away.**

Tell your healthcare provider right away so that a new medicine can be prescribed to control your asthma.

The most common side effects with ALVESCO Inhalation Aerosol include:

- headache
- swelling of nose and throat (nasopharyngitis)
- swelling of the sinuses (sinusitis)
- throat pain
- upper respiratory infection
- joint pain (arthralgia)
- nasal congestion
- pain in arms, legs, and back

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

These are not all of the possible side effects with ALVESCO Inhalation Aerosol. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ALVESCO Inhalation Aerosol?

- Store ALVESCO Inhalation Aerosol at room temperature between 59°F to 86°F (15°C to 30°C)
- **Do not** puncture the ALVESCO Inhalation Aerosol canister
- **Do not** store the ALVESCO Inhalation Aerosol canister near heat or a flame. Temperatures above 120°F (49°C) may cause the canister to burst.
- **Do not** throw the ALVESCO Inhalation Aerosol canister into a fire or an incinerator.
- Safely throw away medicine that is out of date or no longer needed.
- Keep ALVESCO Inhalation Aerosol clean and dry at all times.

Keep ALVESCO Inhalation Aerosol and all medicines out of reach of children.

General Information About the Safe and Effective use of ALVESCO Inhalation Aerosol

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ALVESCO Inhalation Aerosol for a condition for which it is not prescribed. Do not give ALVESCO Inhalation Aerosol to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information summarizes the most important information about ALVESCO Inhalation Aerosol. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about ALVESCO Inhalation Aerosol that is written for health professionals.

For more information, go to www.alvesco.us/.

What are the ingredients in ALVESCO Inhalation Aerosol?

Active ingredient: ciclesonide

Inactive ingredients: propellant HFA-134a and ethanol

Instructions for Use

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(ciclesonide)

Inhalation Aerosol

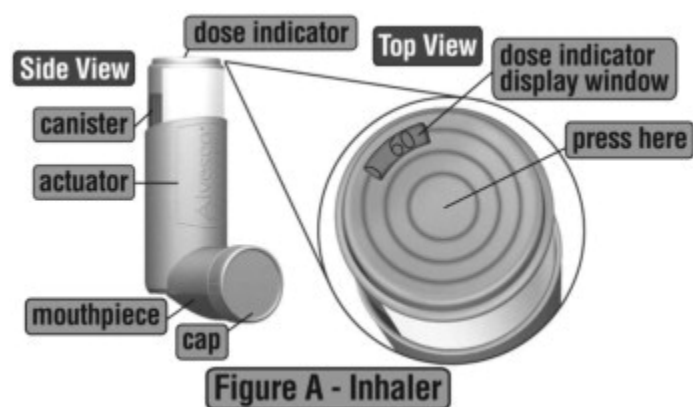
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The parts of your ALVESCO Inhalation Aerosol

ALVESCO Inhalation Aerosol comes as a canister that fits into an actuator with a dose indicator. **Do not** use the actuator with a canister of medicine from any other inhaler. **Do not** use ALVESCO Inhalation Aerosol canister with an actuator from any other inhaler. (See **Figure A**)



Priming your ALVESCO Inhalation Aerosol for use

- Remove your ALVESCO Inhalation Aerosol from its package.
- **Before you use ALVESCO Inhalation Aerosol for the first time** or if you have not used your medicine for 10 days in a row, you will need to prime your ALVESCO Inhalation Aerosol unit.

- Remove the plastic cap. Look at the dose indicator on top of the inhaler. Make sure that the dose indicator display window pointer is before the “60” inhalation mark before you use your ALVESCO Inhalation Aerosol for the first time.
- Hold the actuator upright. Spray 3 times into the air away from the face, by pressing down fully onto the center of the dose indicator button. (See **Figure B**)



Figure B

- Check the dose indicator display window after the priming sprays and before the first use to make sure it shows that there are 60 sprays left in your ALVESCO Inhalation Aerosol unit. If there are not 60 sprays left in your ALVESCO Inhalation Aerosol after the first use priming spray, return it to the pharmacy.
- Make sure the canister is firmly placed in the mouthpiece each time you use your ALVESCO Inhalation Aerosol.
- You do not need to shake your ALVESCO Inhalation Aerosol unit before you use it.

Using Your ALVESCO Inhalation Aerosol

Step 1. Remove the cap from the mouthpiece. (See **Figure C**)

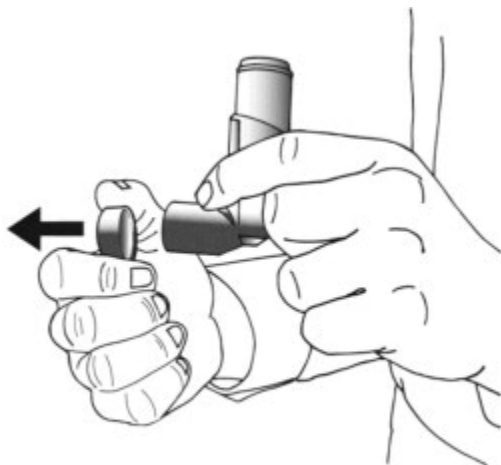


Figure C

Step 2. Hold the actuator upright, between your thumb, forefinger, and middle finger with the mouthpiece pointing towards you. (See **Figure D**)

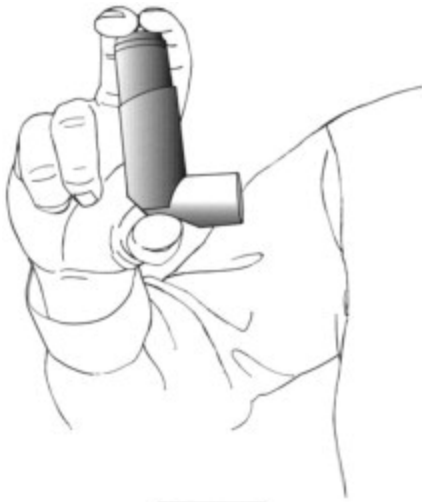


Figure D

Step 3. Breathe out as fully as you comfortably can. Close your lips around the mouthpiece, keeping your tongue below it. (See **Figure E**)



Figure E

Step 4.

- While breathing in deeply and slowly, press down on the center of the dose indicator with your finger. Press down fully on the canister until it stops moving in the actuator 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.

Step 5.

Take your finger completely off the center of the dose indicator and remove the inhaler from your mouth. Breathe out gently. (See **Figure F**)



Figure F

Step 6. Replace the cap to keep the mouthpiece clean.

Step 7. Rinse your mouth with water and spit it out. **Do not** swallow.

Cleaning your ALVESCO Inhalation Aerosol unit

- Clean the mouthpiece weekly with a clean dry tissue, both inside and out. (See **Figure G**)



Figure G

- Wipe over the front of the small hole where the medicine comes out with a dry, folded tissue. (See **Figure H**)

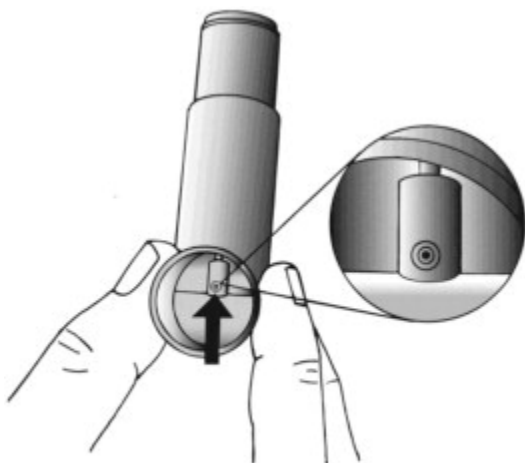


Figure H

- Do not wash or put any part of your ALVESCO Inhalation Aerosol unit in water or any other liquids.

How to tell if your ALVESCO Inhalation Aerosol canister is empty

- Your ALVESCO Inhalation Aerosol unit is fitted with a dose indicator display which shows you how much of your medicine is left after each use.
- Each canister of ALVESCO Inhalation Aerosol contains enough medicine for you to spray your medicine 60 times. This does not count the first sprays used for priming.
- The dose indicator display counts down by 10 and will move every tenth time you take a puff (i.e., 60-50-40, etc.).
- The dose indicator display window will turn red when there are only 20 sprays left. This means that you need to replace your inhaler soon.
- When the dose indicator display window reads “0” you should throw away your ALVESCO Inhalation Aerosol unit. (See **Figure I**)

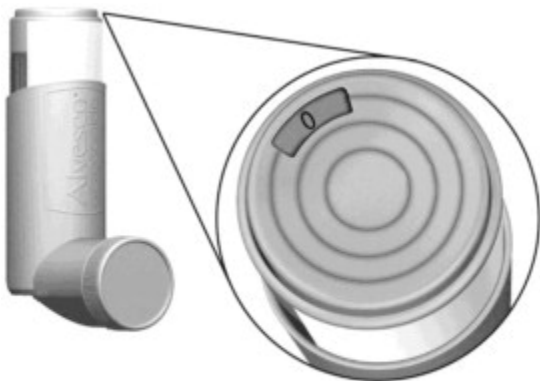


Figure I

- Although your ALVESCO Inhalation Aerosol unit is fitted with a dose indicator display to help determine the number of sprays left, you should keep track of the number of sprays used from each canister of your ALVESCO Inhalation Aerosol unit.

This PPI and Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured for:

Covis Pharma

Zug, 6300 Switzerland

Made in United Kingdom

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