

PART III: CONSUMER INFORMATION

 **ALVESCO**[®]

ciclesonide inhalation aerosol

This leaflet is part III of a three-part "Product Monograph" published when ALVESCO was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ALVESCO. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ALVESCO is used to help breathing problems in asthmatic patients 6 years of age and older.

Asthma is a chronic inflammatory disease of the lungs. People with asthma have episodes of difficulty in breathing. The airways in their lungs are very sensitive. During an asthma attack, the airways get smaller, making it difficult for air to flow in and out of the lungs.

Control of asthma requires avoiding irritants that cause asthma attacks and taking the appropriate medications. For example patients should avoid exposure to house dust mites, mould, pets, tobacco smoke and pollens.

What it does:

ALVESCO is an inhaled (breathed in) medicine. ALVESCO is a corticosteroid that can help ease breathing problems. It relieves swelling and irritation in the small air passages in the lungs.

When it should not be used:

- Do not use this medication if you are allergic to any of the ingredients used in ALVESCO (See "What the medicinal ingredient is" and "What the non-medicinal ingredients are").
- Do not use this medication to treat a sudden attack of breathlessness. You will probably need a different kind of medicine (ie. a fast acting relief medication) in a different colour puffer than may already have been given to you. If you have more than one medicine, be careful not to confuse them.
- Do not use this medication if you have an untreated fungal, bacterial or tuberculosis infection in the respiratory tract.

What the medicinal ingredient is:

ALVESCO contains the medicinal ingredient ciclesonide.

What the non-medicinal ingredients are:

ALVESCO contains ethanol and HFA-134a (a propellant).

What dosage forms it comes in:

ALVESCO comes in two strengths: per spray, 100 micrograms and 200 micrograms.

WARNINGS AND PRECAUTIONS

If you notice the following warning signs, you should contact your physician as soon as possible or go to the nearest hospital:

- A sudden worsening of your shortness of breath and wheezing shortly after using your fast-acting relief medication or after using ALVESCO inhalation aerosol.
- You do not feel relief within 10 minutes after using your fast-acting medication or the relief does not last for at least 3 hours.
- Measurement from your peak flow meter indicates a value less than 60 percent of predicted or personal best.
- You are breathless at rest.
- Your pulse is more than 120 beats per minute.

The following warning signs indicate that your asthma is getting worse and that your treatment needs to be reassessed by your physician:

- A change in your symptoms such as more coughing, attacks of wheezing, chest tightness, or an unusual increase in the severity of the breathlessness.
- You wake up at night with chest tightness, wheezing or shortness of breath.
- You use increasing amounts of your fast-acting relief medication.
- Measurement from your peak flow meter indicates a value between 60 and 80 percent of predicted or personal best.

Pregnancy:

Do not use this medication if you are pregnant, plan to become pregnant or are breastfeeding without first discussing with your doctor.

BEFORE you use ALVESCO talk to your doctor or pharmacist:

- About all health problems you have now or have had in the past.
- If you are suffering from any chest infection (e.g. cold, bronchitis).
- About all the medicines you take, including ones you can get without a prescription.
- If you ever had to stop taking other medicines for asthma because you were allergic to them or had other problems with them.
- If you have a history of tuberculosis (TB) infections.
- If you are taking or have previously taken other steroid medicine by mouth or by inhalation (breathing in).
- If you ever had thrush (a fungal infection) in your mouth.
- If you are taking drugs that suppress the immune system.
- If you have thyroid abnormalities (hypothyroidism).

IMPORTANT: PLEASE READ

- If you have glaucoma or are at risk of developing glaucoma.
- If you have cirrhosis (liver disease).
- If you are taking oral corticosteroids. In rare cases, the withdrawal of oral corticosteroid therapy following the beginning of an inhaled corticosteroid such as ALVESCO, has led to serious hematologic conditions.
- If you have hypoprothrombinemia and are taking acetylsalicylic acid.

INTERACTIONS WITH THIS MEDICATION

Drugs containing ketoconazole (an azole antifungal) have been shown to interact with ALVESCO.

Drugs containing itraconazole (an azole antifungal), or ritonavir and nelfinavir (medicines used to treat HIV infection or AIDS) may interact with ALVESCO.

PROPER USE OF THIS MEDICATION

Usual dose:

Your doctor has explained when and how to take ALVESCO. Follow your doctor's directions carefully.

Adults and Adolescents 12 years of age and older:

The usual dosage for ALVESCO ranges from 100 to 400 micrograms per day. ALVESCO can be taken as 1 or 2 puffs once daily either in the morning or evening.

Some patients with more severe asthma will require 800 micrograms daily, administered as 400 micrograms twice daily.

Children 6-11 years of age:

The recommended dose range is 100 to 200 micrograms per day taken as 1 or 2 puffs once daily either in the morning or evening.

Your doctor will tell you how much ALVESCO to take and how often to take it. You should take ALVESCO daily.

It is very important that you use your medicine regularly to control your asthma. You should continue to take ALVESCO regularly even when you don't have symptoms.

Do not take more doses or use your inhaler more often than your doctor advises.

Do not adjust your dosage without talking to your doctor, even if you think your asthma is under control.

Contact your doctor immediately if your asthma symptoms get worse, or if you need to use your rescue medication more often.

If your doctor decides to stop your treatment, do not keep any leftover medicine unless your doctor tells you to.

Your asthma symptoms can start to improve within 24 hours of starting to use ALVESCO. If your symptoms do not improve within 1-2 weeks, you should talk to your doctor. You should continue to take ALVESCO regularly even when you don't have symptoms. **Do not stop taking ALVESCO suddenly** – even if you feel better. Your doctor can provide you with information about how to slowly stop the medication if necessary.

How to Use ALVESCO Properly:

If your inhaler is new, or if it has not been used for one week or more, you should release three puffs into the air to ensure that it works properly.

You do not need to shake ALVESCO before you use it.

1. Remove the mouthpiece cover.



2. Place the inhaler in your mouth and close your lips around the mouthpiece.
3. Start to breathe in slowly and deeply through your mouth.
4. As you breathe in through your mouth, press down on the top of the inhaler.



5. Move the inhaler away from your mouth and hold your breath for about 10 seconds or as long as is comfortable.
6. Breathe out slowly. Replace the mouthpiece cover. Do not breathe out into the inhaler.



Clean the mouthpiece once a week with a dry tissue, both inside and out. Using a dry, folded tissue, wipe over the front of the small hole where the medicine comes out. Do not use water or any other liquids.

Remember: This medicine is only for you. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

Overdose:

IMPORTANT: PLEASE READ

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

It is very important that you use ALVESCO daily.

However, if you miss one dose, do not worry - just take the next dose when it is due. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Very occasionally, some people find that their throat or tongue becomes sore after taking this medicine or that their voice becomes a little hoarse. In some people, an infection of the mouth and throat called candidiasis (thrush) may occur. Tell your doctor but do not stop treatment unless told to do so. Rinsing your mouth and gargling with water immediately after taking each dose may help. Do not swallow the water after rinsing. Cleaning dentures may also help.

Some patients who take corticosteroids may experience side effects. Side effects are more likely to happen if a patient is taking a high dose of this type of medication. Side effects are also more likely to happen with steroid tablets than with inhaled steroids. Possible side effects are: rounded face, loss of bone density and increased risk of fractures and eye problems.

It is very important that you use your medicine regularly to control your asthma.

Most people who take ALVESCO have no problems. When the drug was tested, some people reported mild, self-limiting side effects. They did not have to stop taking ALVESCO.

Some patients reported:

- hoarseness and difficulty in speaking.
- cough after inhalation.
- nausea or vomiting.
- fungal infection in the mouth.
- headache.
- bad taste, burning, inflammation, irritation, dryness of the mouth or throat.
- skin rash or eczema.

This is not a complete list of side effects. For any unexpected effects or if you feel unwell or have any symptoms that you do not understand while taking ALVESCO, contact your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist	Stop taking drug and call your
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		Only if severe	In all cases	doctor or pharmacist
Common	Sudden wheeziness and chest pain or tightness			X
Rare	Allergic reaction, for example: <ul style="list-style-type: none"> • Swelling of eyelids, face, lips, tongue or throat • Lumpy skin rash or “hives” anywhere on the body 			X
Uncommon	Irregular heart beat (palpitations)		X	
Rare	High blood pressure	X		
Rare	Discomfort or pain in the abdomen	X		

If you notice a sudden worsening of your shortness of breath and wheeze shortly after using your ALVESCO, tell your doctor as soon as possible. As with other medicines taken by inhaling, patients may have increased wheezing immediately after inhaling the drug. In clinical tests with ALVESCO, these reactions have been mostly mild and have disappeared quickly. Use your fast-acting relief medication to treat this reaction.

Some people can be allergic to medicines. If you have any of the following symptoms soon after taking ALVESCO, **stop** taking this medicine and tell your doctor immediately:

- Sudden wheeziness and chest pain or tightness.
- Swelling of eyelids, face, lips, tongue or throat.
- Lumpy skin rash or “hives” anywhere on the body.

HOW TO STORE IT

The canister contains pressurized liquid. Do not pierce or burn it. Store at room temperature (15-25°C) and protect from temperatures above 50°C. Do not freeze. Keep out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

NOTE: This CONSUMER INFORMATION leaflet provides you with the most current information at the time of printing.

The Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at:

www.astrazeneca.ca,

or by contacting the sponsor, AstraZeneca Canada Inc. at: Questions or concerns: 1-800-668-6000.

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Last revised: January 19, 2017