ALVESCO®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ALVESCO?

ALVESCO contains the active ingredient ciclesonide, a corticosteroid. When inhaled, ALVESCO helps to prevent asthma attacks in people aged 6 years and older.

For more information, see Section 1. Why am I using ALVESCO? in the full CMI.

2. What should I know before I use ALVESCO?

Do not use it if you have ever had an allergic reaction to ciclesonide, other steroids or ALVESCO or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you:

- **have any other medical conditions (e.g., immune compromised, not vaccinated for chickenpox or measles or have any type of infection), damage to or recent surgery on the nose, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding or plan to breastfeed**
- **are switching from steroids that you take internally (e.g., by injection or by mouth), to ALVESCO**

For more information, see Section 2. What should I know before I use ALVESCO? in the full CMI.

3. What if I am taking other medicines?

Tell your doctor about any other medicines you are taking. Some medicines may interfere with ALVESCO and affect how it works.

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use ALVESCO?

Inhale ALVESCO into the lungs through your mouth for as long as the doctor tells you. Do not suddenly stop using it.

More information can be found in Section 4. How do I use ALVESCO? in the full CMI.

5. What should I know while using ALVESCO?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using ALVESCO. • Tell your doctor straight away if you feel unwell, have a reaction or experience any serious side effects during or after using ALVESCO (see Section 6. Are there any side effects?). • Keep all your doctor's appointments so that your progress can be checked.
Things you should not do	• Do not suddenly stop using this medicine or change the amount you use without speaking to your doctor first. • Do not use ALVESCO to treat any other complaints unless your doctor tells you to. • Do not give your medicine to anyone else, even if they have the same condition as you.
Looking after your medicine	• Store the pack at room temperature, below 25°C. Do not freeze.

For more information, see Section 5. What should I know while using ALVESCO? in the full CMI.

6. Are there any side effects?

Common side effects may include: headache, fever, redness, swelling, pain or infection in the ear, nose throat or lungs. Other common side effects in children include: feeling or being sick, diarrhoea, upper abdominal pain, toothache. Serious side effects may include: frequent nosebleed, asthma, wheezing or problems breathing and hypersensitivity (allergic) reactions (rash, itching, hives on the skin; swollen face, tongue, throat or other parts of the body; shortness of breath, wheezing or problems breathing).

For more information including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

ALVESCO®

Active ingredient: *ciclesonide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ALVESCO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ALVESCO.**

Where to find information in this leaflet:

1. Why am I using ALVESCO?
2. What should I know before I use ALVESCO?
3. What if I am taking other medicines?
4. How do I use ALVESCO?
5. What should I know while using ALVESCO?
6. Are there any side effects?
7. Product details

1. Why am I using ALVESCO?

ALVESCO contains the active ingredient ciclesonide, a corticosteroid which, when inhaled into your lungs through your mouth, helps to prevent asthma attacks in people aged 6 years and older.

Asthma is a disease where the muscles around the airways become tight (bronchoconstriction) and the lining of the lungs becomes inflamed (swollen and irritated), making it hard to breathe.

When inhaled, ciclesonide acts directly on your air passages to reduce inflammation and help keep the air passages open. In doing so, it helps to improve your condition and to prevent asthma attacks from occurring. It is a "preventer" and needs to be used regularly.

If you have a sudden severe or continuous asthma attack you should use a different fast acting reliever inhaler, which contains a different medicine, to control wheezing or breathlessness, because ALVESCO works as a preventer rather than a reliever inhaler.

ALVESCO will NOT give you immediate relief of wheezing or breathlessness during sudden, severe or continuous asthma attacks. In this situation you should use a fast acting reliever inhaler, which contains a different medicine.

2. What should I know before I use ALVESCO?

Warnings

Do not use ALVESCO if:

- you are allergic to ciclesonide or any of the ingredients listed at the end of this leaflet
- you are having an acute asthma attack
- for children under 6 years of age

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- have had or are currently suffering from any liver problems
- are being treated for any infections
- have or have had tuberculosis (TB)
- are switching from steroids that you take internally (e.g., by injection or by mouth), to ALVESCO
- take any medicines for any other condition

While having ALVESCO, you may be at risk of getting certain side effects. It is important you understand these risks and how to watch for them. See extra information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will talk to you about whether the benefits of having ALVESCO outweigh any possible effects on your unborn baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor will talk to you about whether the benefits of having ALVESCO during breastfeeding outweigh any possible effects on your baby.

Having an operation

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ALVESCO and affect how it works.

Medicines that may interfere with ALVESCO include:

- some antifungal medicines (e.g., ketoconazole, itraconazole)
- some antiviral medicines (e.g., ritonavir, nelfinavir, medicines containing cobicistat)

Your doctor may wish to monitor you carefully if you are taking these medicines

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ALVESCO.

4. How do I use ALVESCO?

How much to use

- ALVESCO is for use by inhaling into the lungs, through your mouth.
- Your doctor will normally start you on 80 micrograms once daily if you are not currently using a preventer medication. Otherwise your starting dose will depend on your current medication and how well your asthma is controlled.
- There are 2 strengths of ALVESCO and your doctor will have chosen the one which best suits your asthma.
- The number of puffs you are required to take daily will depend on the strength of ALVESCO you are using.
- Your doctor may adjust your dose so that you are taking the lowest dose of ALVESCO that will control your symptoms.

How to use the inhaler

Whenever possible, stand or sit in an upright position when inhaling.

If this is a new inhaler or if you have not used your inhaler for one week or more, it must be tested before use by removing the mouthpiece cover and pressing down on the canister inside the inhaler. Release 3 puffs into the air, away from you.

You do not need to shake your inhaler before using your medicine.

The medicine is already in a very fine solution, mixed to ensure you receive the correct dose with each puff.

Follow these instructions carefully and use the pictures to help you.

1 Remove the mouthpiece cover and check inside and outside to make sure that the mouthpiece is clean and dry.



2. Hold the inhaler upright with your forefinger on the top of the canister and your thumb on the base, below the mouthpiece.
3. Breathe out as far as is comfortable.
4. Place the mouthpiece in your mouth and close your lips firmly around it.
5. Just after starting to breathe in through your mouth, press down on the top of the inhaler to release a puff while still breathing in slowly and deeply.



6. Hold your breath, take the inhaler from your mouth and remove your finger from the top of the inhaler. Continue holding your breath for approximately ten seconds or as long as is comfortable.
7. Breathe out slowly through your mouth.



8. If you have been instructed to take another puff, wait about half a minute and repeat steps 3 to 7.
9. After use, always replace the mouthpiece cover to keep out dust.



Replace firmly and snap into position.

It is important that you do not rush steps 3 to 7.

A correct technique will ensure the right amount of ALVESCO is getting into your lungs every time you use your inhaler.

Care and Cleaning instructions

The mouthpiece of your inhaler should be cleaned weekly with a dry tissue or cloth.

DO NOT WASH OR PUT ANY PART OF THE ALVESCO INHALER IN WATER.

You should practice in front of the mirror for the first couple of times until you are confident that you are operating your inhaler properly. Make sure that none of your medicine is escaping from the top of inhaler or sides of your mouth.

If you find it difficult to use the inhaler with one hand, try using both hands. Put your two forefingers on top of the inhaler and both thumbs on the base below the mouthpiece. Tell your doctor, nurse or pharmacist if you are having difficulties.

When the canister is completely empty you will not feel or hear any of the propellant being discharged.

Use of inhaler with a spacer device

If you have problems with your inhaler technique, your doctor may recommend the use of a spacer device in combination with your inhaler. Different brands of spacers may affect the amount of medicine delivered to the lungs, so it is important that you be monitored for any loss of asthma control.

Before use, the spacer should be removed from the inhaler and washed in warm water and detergent and allowed to dry without rinsing or drying with a cloth. Wash the spacer at least monthly after use.

When using a spacer, you should inhale immediately after you press down on the top of the inhaler to release a puff.

Why would your Inhaler have stopped working?

Your inhaler may not work if:

1. the mouthpiece is clogged and dirty

2. the inhaler is empty (check by shaking the canister)
3. the canister is wrongly positioned

If you forget to use ALVESCO

ALVESCO should be used every day at the same time.

If you miss your dose at the usual time, have it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and have your next dose when you are meant to.

Do not have a double dose to make up for the dose you missed.

If you have too much ALVESCO

If you think that you have used too much ALVESCO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ALVESCO?

Things you should do

Tell your doctor straight away if:

- Your asthma symptoms suddenly get worse just after using ALVESCO. Use your fast acting reliever to manage your breathing in the meantime.
- You have severe wheezing or other problems breathing that are not being fixed by your fast-acting reliever inhaler.
- Your eyesight becomes blurred or you have other problems seeing. You may need to have your eyes checked by an eye specialist.
- You become pregnant while you are using ALVESCO.

Other things you should do:

- Keep using ALVESCO every day, even if your asthma is under control.
- Always keep a separate "fast-acting reliever" inhaler handy in case your breathing gets worse. ALVESCO is only used for preventing asthma, not treating it.
- Visit your doctor regularly. This is so they can watch your progress, test your lungs, change the dose if needed, and check any effects on your general health.
- Children and younger adults especially should see their doctor regularly so that they can be watched carefully for any effects on their growth.
- Tell your doctor if your asthma symptoms are getting worse- e.g., if you need to use more of your "fast-acting reliever" inhaler or the effect of your reliever puffers does not last as long as usual.
- Clean your inhaler once a week using a dry cloth or tissue.

Remind any doctor, dentist or pharmacist you visit that you are using ALVESCO.

Things you should not do

- Do not stop using this medicine unless your doctor tells you to. ALVESCO helps control your asthma. Therefore, you must use ALVESCO every day.
- Do not use ALVESCO to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Do not change the amount you use without speaking to your doctor first.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ALVESCO affects you. ALVESCO is unlikely to affect your ability to drive and use machines.

ALVESCO contains alcohol

ALVESCO contains alcohol (ethanol). The amount in two puffs of this medicine is equivalent to less than 1 ml of wine or beer. The small amount of alcohol in this medicine will not have any noticeable effects, however talk to your doctor if you have been told to avoid alcohol for any reason.

Looking after your medicine

- Store the pack at room temperature, below 25°C. Do not refrigerate or freeze.
- Do not puncture or incinerate the canister even when it is empty as it may explode.

Follow the instructions above on how to look after your medicine.

When storing at room temperature, keep it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

When to discard your medicine

- If your doctor or pharmacist tells you to stop using this medicine.
- If it is damaged.
- If the expiry date has passed.
- When you have used all of the doses.

Getting rid of any unwanted medicine

Take it to any pharmacy where it will be disposed of safely.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Digestive system • feeling or being sick (nausea or vomiting) • stomach or abdomen pain • loose stools (diarrhoea) • indigestion **Ear, nose, throat and mouth** • pressure or pain behind the eyes/nose (sinusitis) or ears • red, sore, swollen and/or irritated throat or tonsils, with or without fever • irritated, swollen, stuffy and/or dry nose • nosebleed • toothache • hoarse or lost voice • unpleasant or unusual taste sensation • dry throat or mouth • sore, yellowish, raised patches in the mouth (thrush) **Eyes** • itchy or infected eyes • blurred vision, problems seeing properly or other eye problems such as glaucoma or cataract **General body** • fever (that could mean you have an infection) • flu symptoms • pain in hands, feet, fingers or toes • high blood pressure, thumping heart (this may happen especially if you are also taking other asthma medicines) **Hormones** • Cushing's syndrome (a condition of the adrenal gland) with the following symptoms: round (moon-shaped) face, weight gain, high blood pressure, anxiety, sleeping disorders or increased irritability **Infections**	**Speak to your doctor if you have any of these less serious side effects and they worry you.**
• infections in the throat, airways or lungs that are caused by viruses or bacteria (coughing up yellow sputum may be a sign) • fever, burning feeling when urinating (urinary tract infection) **Lungs** • cough • worsening asthma symptoms (wheezing, cough or other problems breathing), these may be managed by using your fast-acting reliever inhaler **Mental health** • feeling restless, agitated, anxious, hyperactive, depressed, aggressive, having trouble sleeping, or other changes in the way you feel or act **Muscles and bones** • muscle or bone pain • back aches or pains • limited growth (children and adolescents, especially when using ALVESCO for a long time) **Nervous system** • headache **Skin** • skin rash or eczema (dry itchy rash)	

Serious side effects

Serious side effects	What to do
Hypersensitivity (allergic) reaction: • may include rash, itching or hives on the skin, skin redness, swollen face, lips, eyes, tongue or throat or other parts of the body **Lungs** • worsening asthma symptoms (wheezing, cough or other problems breathing), that are **not** managed by the fast-acting reliever inhaler; this may happen straight after using ALVESCO • Pneumonia: fever or chills, increased phlegm/ sputum production or a change in colour, increased cough or problems breathing	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed may occur in some people.

Always speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available with a doctor's prescription.

What ALVESCO contains

Active ingredient (main ingredient)	ciclesonide
Other ingredients (inactive ingredients)	• ethanol • norflurane, a CFC – free propellant
Potential allergens	potassium sorbate

Do not take this medicine if you are allergic to any of these ingredients.

ALVESCO does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

What ALVESCO looks like

ALVESCO is a colourless solution in an aluminium canister with a metering valve.

There are two strengths and two sizes each:

ALVESCO 80 (80 micrograms per puff): 60 or 120 inhalations

ALVESCO 160 (160 micrograms per puff): 60 or 120 inhalations

Not all pack sizes or strengths may be available.

ARTG Numbers:

ALVESCO 80: AUST R 93724

ALVESCO 160: AUST R 93725

Who supplies ALVESCO

Chiesi Australia Pty Ltd
Level 7, Suite 1, 500 Bourke Street,
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