

ALVESCO INHALER

Ciclesonide (80mcg/actuation, 160mcg/actuation)

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What Alvesco is used for

Alvesco is a preventer medication in the treatment of asthma that has to be taken everyday and which becomes active only after it has been inhaled into your lungs.

How Alvesco works

Alvesco contains the active ingredient ciclesonide. Ciclesonide belongs to a group of medicines called corticosteroid. Alvesco is prescribed to control persistent asthma in adult, adolescents and children over 6 years. It helps you to breathe more easily by decreasing the symptoms of your asthma and by lessening the chances of an asthma attack. The effect builds up over a period of time, so this medicine needs to be taken every day, even when you are feeling well.

Before you use Alvesco

- When you must not use it

You should not take Alvesco if you:

- Are allergic to ciclesonide or any of the other ingredients of this medicine. (see section **Product description**).
- Are pregnant or plan to become pregnant. Consult

your doctor first, as he/she will consider the risk and benefit of you taking Alvesco if you are pregnant.

- Are breast-feeding or plan to breastfeed. It is not known if Alvesco passes into your breast milk. You and your doctor should decide if you will take Alvesco or breastfeed. You should not do both without first talking with your doctor.

- Before you start to use it

Before you take Alvesco, tells your doctor if you:

- Have ever been treated, or are currently being treated, for pulmonary tuberculosis (TB), fungal, viral or bacterial infections
- Have severe asthma. Alvesco is not indicated in the treatment of severe or acute episodes of asthma. If you have severe asthma, your doctor may need to carry out regular thorough asthma control checks, including a lung function test.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your doctor if you take:

- Another corticosteroid tablets
- Ketoconazole
- Itraconazole
- Ritonavir
- Nelfinavir

These may intensify the action of Alvesco so that the probability of side effects cannot be completely ruled out.

Other medicines not listed above may also interact with Alvesco. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use Alvesco

- How much to use

Recommended dose range for adults, elderly and adolescent over 12 years with mild to moderate asthma is 160 to 640 mcg per day, which leads to asthma control in the majority of patients. Recommended dose range for children over 6 years is 80 to 160 mcg per day. An increased dosage of Alvesco may become necessary for a short period of time in patients who suffer a severe worsening of their asthma symptoms. This can be up to 1280 mcg per day.

If necessary, your doctor may also prescribe corticosteroid tablets and/or, in the case of an infection, an antibiotic. Your doctor will adjust your dose to the minimum necessary to control your asthma. You should start to notice an improvement in your symptoms (wheezing, tight chest and coughing) within 24 hours.

- When you use it

For once daily dosing, Alvesco should preferably be administered in the evening although morning dosing of Alvesco has also been shown to be effective. Please consult and follow your doctor's advice. Follow your doctor's instructions very carefully. It is important that you take Alvesco regularly every day, even if you feel better.

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If you find that you have to use your reliever inhaler more than 2-3 times a week, you should contact your doctor to have your medicine reviewed.

- How long to use it

Continue taking Alvesco for as long as your doctor recommends.

- If you forget to use it

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take only your next regularly scheduled dose. Do not take 2 doses at the same time.

- If you use too much (overdose)

There is no specific treatment necessary if you have used too much Alvesco but you should inform your doctor. If high doses are used over a long period, a certain degree of reduction in adrenal function cannot be ruled out and control of the adrenal function may be necessary.

While you are using it

- Things you must do

- It is important that a doctor, nurse or pharmacist shows you first how to use your Alvesco inhaler properly. A good technique will make sure you are receiving the correct amount into your lungs. If you have a new inhaler, or if you have not used your inhaler for a week or more, it must be tested before you use it. Remove the mouthpiece cover and press down three times on the canister inside the inhaler to release three puffs into the air - away from you.
- Please clean the mouthpiece regularly 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.

- Things you must not do

- Do not stop taking Alvesco without first checking with your doctor.
- Do not give Alvesco to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

If you begin to feel wheezy or tightness in the chest after using your Alvesco inhaler:

- Do not take any more puffs.
- Use your reliever inhaler to help your breathing.
- Contact your doctor immediately.

If you find it difficult to use the inhaler, your doctor may recommend the use of a spacer. The spacer that fits the Alvesco inhaler is called AeroChamber Plus™. If you use the AeroChamber Plus™ device, please follow the instructions provided with it. Your doctor or pharmacist will be able to advise you about the device.

Side effects

Uncommon side effects with Alvesco include:

- Burning, inflammation, irritation and dryness of mouth or throat
- Oral fungal infections
- Headache
- Bad taste
- Nausea or vomiting
- Rash or eczema
- Cough after inhalation

Rare side effects may include:

- Sensation of heartbeat (palpitations)
- Discomfort or pain in the abdomen
- High blood pressure
- Indigestion
- Swelling under the skin (angioedema)

Taken long period of time, Alvesco may affect normal production of corticosteroids, the effect may include:

- Reduced rate of growth in adolescents
- A thinning of the bones
- Cataracts and glaucoma
- Moon-shaped face, weight gain in the upper body and others features of Cushingoid or Cushing syndrome.

Adolescents who are receiving treatment for a long period of time should have their height checked regularly by their doctor. If your growth rate is slowed, your doctor will adjust your treatment if possible to the lowest dose at which effective control of asthma is maintained.

Corticosteroid tablets can lead to more side effects than a corticosteroid inhaler such as Alvesco. If you have been taking steroid tablets before or during the use of Alvesco, the risk of side effects from the tablets may continue for a period of time. Regular check-ups with your doctor will ensure that you are taking the right dose of Alvesco for you. Regular check-ups will also identify any side effects early on and reduce the chances of them worsening.

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Alvesco. For more

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information, ask your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Alvesco

- Storage

Keep out of reach and sight of children. Store Alvesco below 30°C. Do not expose to temperatures higher than 50°C.

Container contains pressurized liquid. Should not punctured, broken or burned even if it is seems empty.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Alvesco is a clear and colourless aerosol spray. It is supplied in HFA-134a propellant and ethanol.

- Ingredients

- Active ingredient – Ciclesonide.
- Inactive ingredients – Ethanol and norflurane (HFA-134a).

- MAL Number

MAL20051456AZ
Alvesco 80 Inhaler (120 puffs)
MAL20051457AZ
Alvesco 160 Inhaler (120 puffs)
MAL20051458AZ
Alvesco 80 Inhaler (60 puffs)
MAL20051459AZ
Alvesco 160 Inhaler (60 puffs)
- (Marketed)

Manufacturer

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Product Registration Holder

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