Package leaflet: Information for the user

[Invented name] 80 micrograms/dose pressurised inhalation, solution
[Invented name] 160 micrograms/dose pressurised inhalation, solution
[Invented name] 320 micrograms/dose pressurised inhalation, solution

ciclesonide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Invented name] is and what it is used for

What [Invented name] is
[Invented name] is a clear and colorless aerosol spray for you to breathe in through your mouth and into your lungs. It is a preventive medication (corticosteroid) that has to be taken every day and which becomes active only after it has been inhaled into your lungs.

What [Invented name] is used for
[Invented name] is used to treat persistent asthma in adult and adolescent patients (12 years old and older).

How [Invented name] works
[Invented name] 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.

This medicine is not suitable for use in an acute attack of breathlessness. For quick relief from such an attack, use only your Reliever inhaler.

2. What you need to know before you use [Invented name]

Do not use [Invented name]
- if you are allergic to ciclesonide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using [Invented name].

- Before beginning treatment with this medicine, please tell your doctor if:

you have ever been treated, or are currently being treated, for pulmonary tuberculosis (TB), fungal, viral or bacterial infections.

Check with your doctor if you are not sure. It is important to make sure that [Invented name] is the right medicine for you.

During your treatment with [Invented name] contact your doctor immediately if:
- breathing becomes difficult and your symptoms, coughing, breathlessness, wheezing, tightness in the chest, increasing noises (rhonchi) or other symptoms of narrowing of the airways are getting worse. (You should use your Reliever inhaler which will normally lead quickly to an improvement.)
- you are waking up at night with your symptoms.
- you are not getting relief from using your Reliever inhaler.

Your doctor will decide on your further treatment.

Contact your doctor if you experience blurred vision or other visual disturbances.

Specific patient groups
Patients with severe asthma are at risk of acute asthma attacks. For such patients the doctor will carry out regular thorough asthma control checks, including a lung function test.

Patients who are already taking corticosteroid tablets:
[Invented name] can be used to replace your tablets, or to reduce the number of tablets you need to take. Please follow your doctor's instructions carefully.
- This will start about a week after you begin your [Invented name] inhalations.
- The number of tablets you take will be reduced with caution over a period of time.
- During this period you may sometimes suffer from a general feeling of being unwell.
- In spite of this, it is important to continue both with your [Invented name] inhalations and with slowly reducing the number of tablets you take.
- If you get serious symptoms such as nausea (feeling sick), vomiting (being sick), diarrhoea or a high temperature, contact your doctor.
- This process may sometimes reveal minor allergies such as rhinitis (inflammation of the inside of the nose) or eczema (itchy, reddening skin).
- If you have changed over from tablets, you will continue for a time to be at risk of reduced adrenal function, which is related to the corticosteroid tablets you take. The symptoms of reduced adrenal function (e.g. dizziness, fainting, nausea, loss of appetite, moodiness, decrease in body hair, inability to cope with stress, weakness, headaches, memory problems, allergies, food cravings, and blood sugar disorders) may also continue for some time.
- You may also need to see a specialist to determine the extent of the reduction in adrenal function.
- Your doctor will also do regular checks on your adrenal function.
- During periods of stress, for example, having an operation, worsening asthma attacks, it is possible that you will need extra corticosteroid tablets. **If so, you must carry a steroid warning card** which says so.

Patients with liver or kidney disorders
There is no need to adjust the dose of ciclesonide if you have liver or kidney problems. If you suffer from a severe liver condition, your doctor will check you more carefully for possible side effects resulting from disturbance of normal steroid production.

Children below 12 years of age
This medicine is not recommended for children below the age of 12 because of a lack of information about its possible effects.

Other medicines and [Invented name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Please inform your doctor before using [Invented name], if you are currently being treated for any fungal or viral infections with medicine containing:
- ketoconazole,

- itraconazole,
- ritonavir,
- nelfinavir.

These may intensify the action of [Invented name] so that the probability of side effects cannot be completely ruled out.

[Invented name] with food and drink
There is no interaction between [Invented name] and food and drink.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Because there is not enough information about the effects of [Invented name] on pregnant women, your doctor will discuss with you the risks and benefits of using [Invented name].
- Ciclesonide (the active ingredient in [Invented name]) may be taken during pregnancy only when the possible benefits to the mother justify the possible risk to the developing baby. If your doctor decides that you can continue using [Invented name], the smallest possible dose of ciclesonide will be used to maintain asthma control.
- The adrenal function will be carefully monitored in children of mothers who received corticosteroids during pregnancy**.**
- Talk to your doctor if you want to use [Invented name] during breast-feeding.
- It is not known whether inhaled ciclesonide passes into the breast milk in humans.
- Prescribing [Invented name] to women who are breast-feeding will therefore only be considered if the expected benefit to the mother outweighs the possible risk to the child.

Driving and using machines
[Invented name] has no or negligible effects on the ability to drive or to use machinery.

[Invented name] contains ethanol
This medicine contains 4.7 mg of alcohol (ethanol) in each dosage. The amount in a dose of this medicine is equivalent to less than 1 ml beer or wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to use [Invented name]

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- If you have just started to use this medicine instead of, or as well as, taking corticosteroid tablets, see section 2, Patients who are already taking corticosteroid tablets.

How much [Invented name] should I take each day?
Your doctor will have spoken to you about how much of your medicine you need to take each day.
This will depend on your individual need.

- The recommended dose of [Invented name] is 160 micrograms once daily, which leads to asthma control in the majority of patients.

- In some patients a dose reduction to 80 micrograms, once daily, may be an adequate dose for maintaining effective control of their asthma.

- An increased dosage of [Invented name] 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 640 micrograms per day, delivered as 320 micrograms twice daily but no data confirming the additional therapeutic effect after 3 months with these higher doses are available.

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 should I use my [Invented name] inhaler?
In most cases, either in the morning or in the evening – as one or two puffs once a day. Follow your doctor's instructions very carefully. It is important that you take [Invented name] regularly every day, even if you feel better.

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 do I use my [Invented name] inhaler?
It is important that a doctor, nurse or pharmacist shows you first how to use your [Invented name] inhaler properly. A good technique will make sure you are receiving the correct amount into your lungs.
Please use the instructions in this leaflet as a reminder.

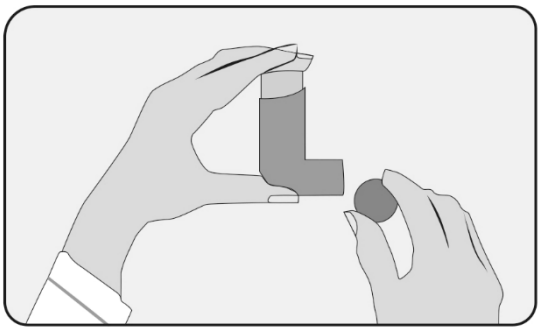
You may wish to practice in front of the mirror for the first couple of times until you are confident that you are using your [Invented name] inhaler properly. Make sure that none of your medicine is escaping from the top or sides of your mouth.

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.

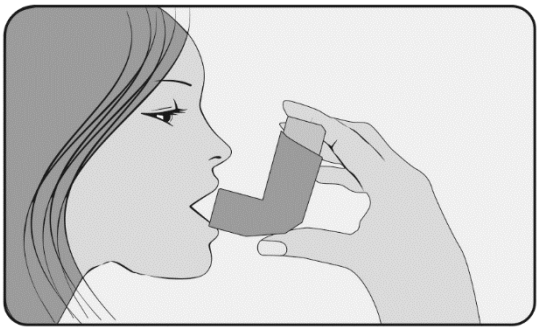
You do not need to shake your [Invented name] inhaler before using it. The medicine is already in a very fine solution, mixed to ensure you receive the correct dose with each puff.

During inhalation, you can either be sitting down or standing up.

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



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

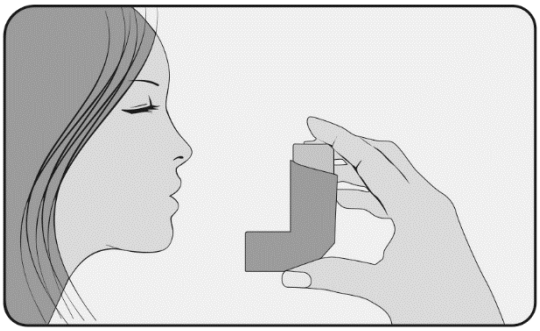


2. Hold the inhaler upside down (base of the canister at the top) with your forefinger on the base of the canister and your thumb under the mouthpiece.

3. Breathe out as far as is comfortable. Do not breathe out through the inhaler.

4. Place the mouthpiece in your mouth and close your lips firmly around it.

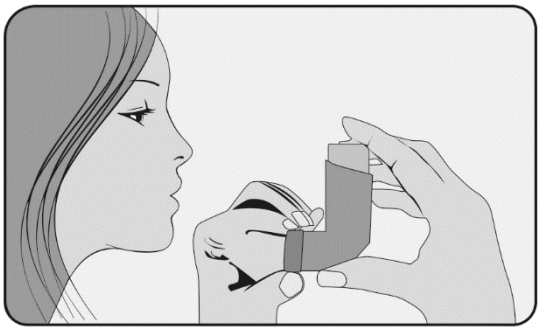
5. Just after starting to breathe in through your mouth, press down with your forefinger on the top of the inhaler to release a puff of the medicine while you are still breathing in slowly and deeply. Please take care that the puff of medicine does not escape through the top, bottom or sides of your mouth.



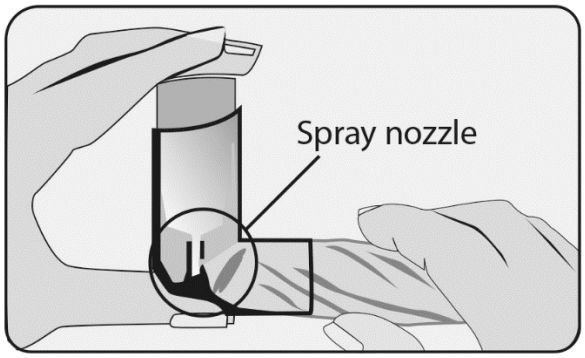
6. Hold your breath, take the inhaler from your mouth and remove your finger from the top of the inhaler. Continue holding your breath for about ten seconds or as long as is comfortable. Breathe out slowly through your mouth. Do not breathe out through the inhaler.

It is important that you do not rush steps 3 to 6.

7. If you have been instructed to take another puff, **wait** about half a minute and **repeat** steps 3 to 6.



8. After use, always replace the mouthpiece cover to keep out dust. Replace firmly and snap into position.



For hygiene reasons please clean the mouthpiece weekly with a dry tissue, both inside and out.

1. Remove the mouthpiece cover, do not remove the inhaler from the plastic actuator;
2. Using a dry, folded tissue, wipe over the front of the small hole where the medicine comes out.
3. Do not use water or any other liquids.

A correct technique will ensure the right amount of [Invented name] is getting into your lungs every time you use your inhaler. Your doctor will check your inhalation technique regularly to ensure that your treatment can have the very best effect.

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

If you begin to feel wheezy or tightness in the chest after using your [Invented name] 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 [Invented name] 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.

If you use more [Invented name] than you should

It is important that you take your dose as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.
There is no specific treatment necessary if you have used too much [Invented name] but you should inform your doctor. If high doses are used over long periods, a certain degree of reduction in adrenal function cannot be ruled out and control of the adrenal function may be necessary.

If you forget to use [Invented name]

If you have forgotten to use your [Invented name], just take your usual dose when it is next due. Do not take a double number of puffs to make up for the forgotten dose.

If you stop using [Invented name]

Even if you feel better, you should not stop using your [Invented name] inhaler.
If you do stop using this medicine, you must tell your doctor immediately.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
If you notice any of the following serious side effects, stop using this medicine and talk to your doctor straight away:

- severe allergic reactions such as swelling of lips, tongue and throat (may affect up to 1 in 1,000 patients treated)
- allergic reactions: skin rashes, redness, itching or weals like nettle rash and hives (may affect up to 1 in 100 patients treated)
- cough, or wheezing, which gets worse soon after taking an inhalation (may affect up to 1 in 100 patients treated).

The other side effects seen with [Invented name] are usually mild. In most cases you can continue with your treatment. The side effects you may experience are:

Uncommon side effects (may affect up to 1 in 100 patients treated):
- hoarseness
- burning, inflammation, irritation of mouth or throat
- oral thrush (oral fungal infection)
- headache
- bad taste
- dryness of mouth or throat
- nausea or vomiting.

Rare side effects (may affect up to 1 in 1,000 patients treated):
- sensation of heartbeat (palpitations)
- discomfort or pain in the abdomen
- high blood pressure.

Not known (frequency cannot be estimated from the available data):
- sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur in children
- blurred vision.

[Invented name] may affect the normal production of corticosteroids in your body. This is usually seen in patients taking high doses over a long period of time. These effects may include:
- reduced rate of growth in adolescents
- a thinning of the bones
- possible clouding of the lens of the eye (cataracts) causing blurred vision
- loss of vision caused by abnormally high pressure in the eye (glaucoma)
- moon-shaped face, weight gain in the upper body and thinning arms and legs (Cushingoid features 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 [Invented name]. If you have been taking steroid tablets before or during the use of [Invented name], 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 [Invented name] for you. Regular check-ups will also identify any side effects early on and reduce the chances of them worsening.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

The container contains a pressurised liquid. Do not store above 50°C.
The container should not be punctured, broken or burned even if it seems empty.

As with most inhaled medicines in pressurised containers, the healing effect of this medicinal product may become smaller when the container is cold. However, [Invented name] delivers the same level of dose from minus 10°C to plus 40°C.
If the inhaler gets very cold, take the inhaler out of the plastic case and warm it in your hands for few minutes before use. Never use anything else to warm it up.

If your doctor decides to stop treatment or if the inhaler is empty, return it to your pharmacist for safe disposal. This is important as traces of medicine could remain in the container even if you have the impression that it might be empty.

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

6. Contents of the pack and other information

What [Invented name] contains
- The active substance is ciclesonide. Each actuation releases a puff (dose delivered through the mouthpiece) that contains either 80, 160 or 320 micrograms of ciclesonide.
- The other ingredients are: anhydrous ethanol and propellant (HFA-134a (norflurane)).

This medicine contains fluorinated greenhouse gases. Each inhaler contains 8.8 g of norflurane corresponding to 0.0126 tonne CO_2 equivalent (global warming potential GWP = 1430).

What [Invented name] looks like and contents of the pack
[Invented name] consists of a clear and colourless liquid in a pressurised aluminium container which delivers through a mouthpiece an accurately measured dose of ciclesonide in the form of a spray.

Pack size:
Inhaler with 120 puffs.

Marketing Authorisation Holder and Manufacturer
[To be completed nationally]

This leaflet was last revised in

10 Oct 2025

Other sources of information

Detailed information on this medicine is available on the web site of {MA/Agency}