

Package leaflet: Information for the patient

Beclazone 100, 250 micrograms Easi-Breathe® CFC-Free Inhaler Pressurised Inhalation Solution

beclometasone dipropionate

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 Beclazone Easi-Breathe® CFC-Free Inhaler is and what it is used for
2. What you need to know before you use Beclazone Easi-Breathe® CFC-Free Inhaler
3. How to use Beclazone Easi-Breathe® CFC-Free Inhaler
4. Possible side effects
5. How to store Beclazone Easi-Breathe® CFC-Free Inhaler
6. Contents of the pack and other information

1 What Beclazone Easi-Breathe® CFC-Free Inhaler is and what it is used for

Beclazone Easi-Breathe® CFC-Free Inhaler contains the active substance beclometasone dipropionate, which belongs to a group of medicines called corticosteroids. (often just called steroids). A very small dose of steroid is needed when it is inhaled. This is because it is inhaled straight to your lungs.

Beclazone Easi-Breathe® CFC-Free Inhaler works by reducing swelling and irritation in the lungs. It has what is called an 'anti-inflammatory action'.

Beclazone Easi-Breathe® CFC-Free Inhaler helps to prevent asthma attacks in people who need regular treatment. This is why it is sometimes called a 'preventer'. It needs to be used regularly, every day.

Beclazone Easi-Breathe® CFC-Free Inhaler will not help treat sudden asthma attacks where you feel breathless.

- A different medicine is used for treating sudden attacks (called a 'reliever').
- If you have more than one medicine, be careful not to confuse them.

Beclazone Easi-Breathe® CFC-Free Inhaler is supplied to you in an inhaler. You breathe the medicine directly into your lungs.

Beclazone Easi-Breathe® CFC-Free Inhaler contains norflurane. This is less harmful to the environment than older inhalers. Older inhalers may taste differently to Beclazone Easi-Breathe® CFC-Free Inhaler. This will make no difference to how your medicine works. It also contains small amounts of ethanol (alcohol). At the usual dose, this amount is so small that it should not cause any problems.

2 What you need to know before you use Beclazone Easi-Breathe® CFC-Free Inhaler

Do not use Beclazone Easi-Breathe® CFC-Free Inhaler:

- if you are allergic to beclometasone dipropionate (active ingredient) 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 Beclazone Easi-Breathe[®] CFC-Free Inhaler if:

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- you suffer from or have ever suffered from tuberculosis (TB).
- you have ever had thrush (candidiasis) in your mouth.
- you are using Beclazone Easi-Breathe[®] CFC-Free Inhaler at the same time as taking steroid tablets or injections. Also, if you have just finished taking steroid tablets or injections. In both cases, you should carry a steroid warning card until your doctor tells you not to carry one.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before using Beclazone Easi-Breathe[®] CFC-Free Inhaler.

If your breathing or wheezing gets worse straight after using Beclazone Easi-Breathe[®] CFC-Free Inhaler, **stop using it and tell your doctor immediately.**

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

Because your inhaler is used to prevent asthma attacks, it is important to use it regularly, even when you feel well.

It may take a few days for this medicine to work. Do not stop using your inhaler unless you are told to by a doctor.

Consult a doctor immediately if your usual treatment is not working. Your doctor will tell you if you need any extra treatment. Your dosage should only be increased on medical advice.

Other medicines and Beclazone Easi-Breathe[®] CFC-Free Inhaler

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you have to go into hospital.

The following medicines may influence the effect of Beclazone Easi-Breathe[®] CFC-Free Inhaler:

- Other asthma medicines, such as bronchodilators, or other corticosteroids in tablet form.

Some medicines may increase the effects of Beclazone Easi-Breathe[®] CFC-Free Inhaler and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

If you are taking metronidazole (an antibiotic) or disulfiram (a treatment for alcohol dependency), please speak with your doctor before taking Beclazone Easi-Breathe[®] CFC-Free Inhaler.

Beclazone Easi-Breathe[®] CFC-Free Inhaler with food and drink

You can use Beclazone Easi-Breathe[®] CFC-Free Inhaler at any time of day, with or without food.

Pregnancy and breast-feeding

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.

Beclazone Easi-Breathe[®] CFC-Free Inhaler should only be used if recommended by a doctor.

Driving and using machines

Beclazone Easi-Breathe[®] CFC-Free Inhaler is not likely to affect you being able to drive or use any tools or machines.

Beclazone 100 micrograms Easi-Breathe[®] CFC-Free Inhaler:

This medicine contains 3.11 mg of alcohol (ethanol) in each metered dose. The amount in each metered dose of this medicine is equivalent to less than 0.5 ml beer or wine.

Beclazone 250 micrograms Easi-Breathe[®] CFC-Free Inhaler:

This medicine contains 6.00 mg of alcohol (ethanol) in each metered dose. The amount in each metered dose of this medicine is equivalent to less than 0.5 ml beer or wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

3 How to use Beclazone Easi-Breathe[®] CFC-Free Inhaler

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

All patients are different and your doctor may have prescribed a different dose for you.

Using this medicine

- Beclazone Easi-Breathe[®] CFC-Free Inhaler is for inhalation by mouth only.
- Instructions on how to use the inhaler are given as a step-by-step guide below.
- It takes a few days for this medicine to work and it is very important that you use it regularly.
- Do not stop using it even if you feel better, unless told to do so by your doctor.
- Do not use more than you are told.
- Do not use this medicine to treat a sudden attack of breathlessness – it will not help you. You should use a quick-acting reliever inhaler (e.g. salbutamol) for this purpose.

The recommended dose for Beclazone Easi-Breathe[®] CFC-Free Inhaler is:

Adults and adolescents 12 years and over

Beclazone 100 micrograms Easi-Breathe[®] CFC-Free Inhaler: Take one to two puffs twice daily. Usually the most you would take in 24 hours is eight puffs.

Beclazone 250 micrograms Easi-Breathe[®] CFC-Free Inhaler: Take one to two puffs twice daily. Usually the most you would take in 24 hours is four puffs.

Use in children (7-12 years)

Beclazone 100 micrograms Easi-Breathe[®] CFC-Free Inhaler: Take one to two puffs twice daily. Usually the most you would take in 24 hours is four puffs.

Beclazone 250 micrograms Easi-Breathe[®] CFC-Free Inhaler is not recommended for use in children.

Hepatic or renal impairment

Dose adjustments are not required. Follow your doctor's instructions.

If you are using high doses of an inhaled steroid for a long time you may sometimes need extra steroids for example during stressful circumstances such as a road traffic accident or before an operation. Your doctor may decide to give you extra steroid medicines during this time.

Instructions for use of the inhaler

Important

Before using your inhaler, please read this leaflet carefully and follow the instructions. If you are not sure how or when to use your inhaler, ask your doctor or a pharmacist.

Do not stop using your inhaler unless your doctor tells you to. If your doctor tells you to stop using your inhaler, take any inhalers you have left back to your pharmacist.

Using the Inhaler

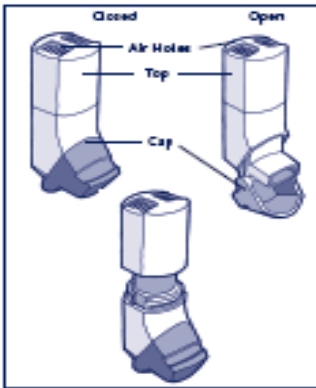
Beclazone Easi-Breathe[®] CFC-Free Inhalers have been designed to make it easier for you to use. It is a breath-operated inhaler. This means that it only releases a dose when you breathe in.

Important

Before you use your inhaler, please read this leaflet carefully and follow the instructions. Do not rush steps 3 and 4 below. It is important that you start to breathe in as slowly as possible before you start using your inhaler. Practice in front of a mirror for the first few times. If you see 'mist' coming from the top of the inhaler or from the sides of your mouth, you should start again from step 2.

Opening

To open the inhaler, fold down the cap, which fits over the mouthpiece.



Test spray the inhaler before you use it for the first time and also if you have not used the inhaler for five days. To test spray your inhaler, unscrew the top of it so that you can see the metal can inside.

Open the cap, shake the inhaler and spray the aerosol by pressing the can with your finger or thumb.

Close the cap and put the top back on.

1. Before use, shake the inhaler vigorously.



2. Hold the inhaler upright and open it by folding down the cap that fits over the mouthpiece.



3. Breathe out normally as far as you comfortably can. Then hold the mouthpiece firmly between your lips. Hold the inhaler upright and make sure that your hand is not blocking the airholes. Breathe in slowly and deeply through the mouthpiece. Don't stop breathing when the inhaler puffs the dose into your mouth. Carry on until you have taken a deep breath.



4. Take the inhaler out of your mouth and hold your breath for 10 seconds, or for as long as you comfortably can. Breathe out slowly.



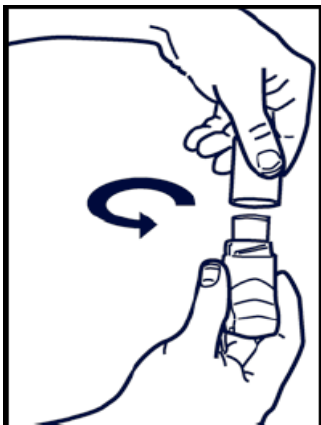
5. After you have used your inhaler, hold it upright and immediately close the cap.
6. If you need to take more than one puff, close the cap, wait at least one minute between doses and then repeat the process from Step 1.

Cleaning the inhaler

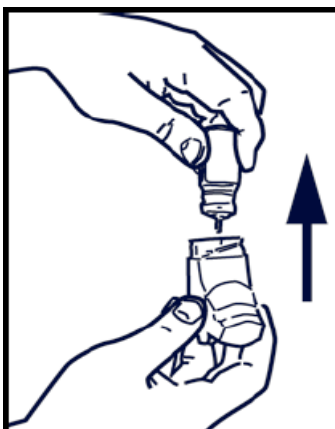
You must keep your inhaler clean, especially the mouthpiece. This will prevent deposits from the aerosol building up.

CLEAN YOUR INHALER AT LEAST ONCE A WEEK.

- A. Unscrew the top of your inhaler. Keep this top dry at all times.



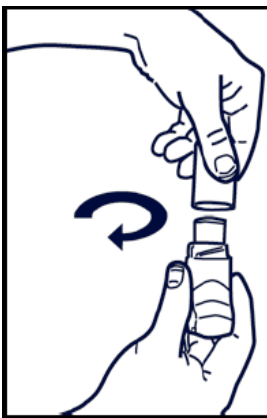
- B. Remove the metal can. Do not put the metal can in water.



- C. Rinse the inhaler body in warm water and dry it (leave to dry overnight if possible). Do not use very hot water.



D. Put the metal can back in your inhaler and close the cap. Screw the top of your inhaler back onto the body. Do not wash the top part of the inhaler. Do not use any heat to dry the inhaler body.



Failure to allow the mouthpiece to dry properly will result in your inhaler becoming blocked.

What to do if your breathing gets worse

If you notice that you are more short of breath and your wheeze is getting worse, tell your doctor immediately. He or she will tell you if you need any extra treatment.

If you take more Beclazone Easi-Breathe[®] CFC-Free Inhaler than you should

If you use more than you should, talk to your doctor as soon as possible.

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.

If you forget to take Beclazone Easi-Breathe[®] CFC-Free Inhaler

Do not take a double dose to make up for a forgotten dose. If you forget to use your inhaler, take your recommended number of puffs when you remember. Then continue your treatment as prescribed by your doctor.

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

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. You may need urgent medical treatment.

- allergic reactions (may affect up to 1 in 100 people) – the signs include skin rashes, redness, itching or weals like nettle rash or hives
- severe allergic reactions (may affect up to 1 in 10,000 people) - the signs include swelling of your face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed and collapse
- your breathing or wheezing gets worse straight after using your inhaler

Talk to your doctor as soon as possible if:

- after 7 days of using Beclazone Easi-Breathe® CFC-Free Inhaler your shortness of breath or wheezing does not get better, or gets worse.

Other side effects include:

Very common: may affect more than 1 in 10 people

Candidiasis (thrush) in the mouth and throat, which is seen as white spots.

Common: may affect up to 1 in 10 people

Hoarseness of the voice and sore throat.

Problems with your mouth and throat can be reduced by doing certain things straight after inhaling your dose. These are brushing your teeth, rinsing your mouth or gargling with water and spitting it out. Tell your doctor if you have these problems with your mouth or throat, but do not stop treatment unless you are told to.

Uncommon: may affect up to 1 in 100 people

Itching, rash and reddening of the skin.

Rare: may affect up to 1 in 1,000 people

Wheezing, difficulty in breathing or tightness in your chest. If this happens, stop using your inhaler and tell your doctor immediately.

Very rare: may affect up to 1 in 10,000 people

- Sleeping problems or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur in children. The way steroids are produced by your body may be affected when using Beclazone Easi-Breathe® CFC-Free Inhaler. This is more likely to happen if you use high doses for a long period of time. This can cause:
 - children and young people to grow more slowly.
 - something called ‘Cushing’s syndrome’. This happens when you have too much steroid in your body and it can cause thinning of your bones and eye problems (such as cataracts and glaucoma).
 Your doctor will help stop this happening by making sure you use the lowest dose of steroid which controls your symptoms.

Frequency not known, but may also occur

- Depression or aggression. These effects are more likely to occur in children.
- Blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Beclazone Easi-Breathe® CFC-Free Inhaler

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.

Do not store above 25°C.

Do not refrigerate or freeze. If your inhaler gets very cold, remove the metal can and warm it in your hands for a few minutes before you use it. Do not warm the can in any other way.

Pressurised aerosol can. Do not expose to temperatures higher than 50°C. Do not puncture, break or burn the can, even if it seems empty.

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.

6 Contents of the pack and other information

What Beclazone Easi-Breathe® CFC-Free Inhaler contains

- The active substance is beclometasone dipropionate.

Each puff (metered dose) of Beclazone 100 micrograms Easi-Breathe® CFC-Free Inhaler contains 100 micrograms of beclometasone dipropionate.

Each puff (metered dose) of Beclazone 250 micrograms Easi-Breathe® CFC-Free Inhaler contains 250 micrograms of beclometasone dipropionate.

- The other ingredients are ethanol anhydrous (alcohol) and the propellant norflurane (HFA-134a). This medicine does not contain any CFCs.

What Beclazone Easi-Breathe® CFC-Free Inhaler looks like and contents of pack

- The name of your medicine is

Beclazone 100 micrograms Easi-Breathe® CFC-Free Inhaler Pressurised Inhalation Solution

Beclazone 250 micrograms Easi-Breathe® CFC-Free Inhaler Pressurised Inhalation Solution

- Each pack of Beclazone Easi-Breathe® CFC-Free Inhaler contains a single inhaler that supplies 200 breath-operated doses.
- For inhalation use. Pressurised Inhalation, Solution.

Marketing Authorisation Holder and Manufacturer:

Norton Waterford T/A IVAX Pharmaceuticals Ireland

IDA Industrial Park

Waterford

Ireland

This medicinal product is authorised in the Member States of EEA under the following names:

Ireland: Beclazone 100, 250 micrograms Easi-Breathe® CFC-Free Inhaler Pressurised Inhalation Solution

This leaflet was last revised in August 2023.