

Package leaflet: Information for the patient
Beclazone[®] 200 micrograms 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 or pharmacist.
- This medicine has been prescribed for you. Do not pass it to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Beclazone CFC-Free Inhaler is and what it is used for

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

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

Beclazone CFC-Free Inhaler contains norflurane. This is less harmful to the environment than older inhalers. Older inhalers may taste differently to Beclazone 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 CFC-Free Inhaler

Do not use Beclazone CFC-Free Inhaler

- If you are allergic to beclometasone dipropionate (active ingredient) or to 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 CFC-Free Inhaler if:

- you suffer from or have ever suffered from tuberculosis (TB).

- you have ever had thrush (candidiasis) in your mouth.
- you are using Beclazone 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 CFC-Free Inhaler.

If your breathing or wheezing gets worse straight after using Beclazone 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 CFC-Free Inhaler

Tell your doctor, nurse or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines that you 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 CFC-Free Inhaler:

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

Some medicines may increase the effects of Beclazone 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 CFC-Free Inhaler.

Beclazone CFC-Free Inhaler with food and drink

You can use Beclazone 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 CFC-Free Inhaler should only be used if recommended by a doctor.

Driving and using machines

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

This medicine contains 5.13 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 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 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 usual dose for Beclazone CFC-Free Inhaler is:

Adults and the elderly:

Take one to two puffs twice daily.

Usually the most you would take in 24 hours is five puffs.

Beclazone 200 micrograms 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 carefully. 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.

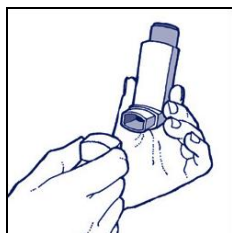
If you find it difficult to use your inhaler with one hand, as shown in the diagrams, use both hands. You must spray your inhaler at the same time as you breathe in.

Children may need help to use Beclazone CFC-Free Inhaler. Parents can help by spraying the aerosol when the child begins to breathe in.

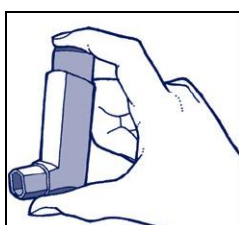
Using the Inhaler

Test spray the inhaler before you use it for the first time and also if you have not used the inhaler for five days.

1. Take the cap off the inhaler. Make sure the mouthpiece is clean and free of fluff and dirt.



2. Hold the inhaler upright with your thumb on the base and your first finger on the top of the can. Shake the inhaler vigorously up and down.



3. Breathe out normally as far as you comfortably can. Then hold the mouthpiece firmly between your lips. Breathe in slowly and deeply. As you first start to breathe in, press the aerosol can with your first finger to spray the aerosol and release the medicine. Continue to breathe in slowly and deeply.



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. If you need more than one puff, wait for about one minute and then start again from step 2. Put the cap back on the inhaler.

Note

Do not rush step 3. It is important that you start to breathe in as slowly as possible just before 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.

Cleaning the inhaler

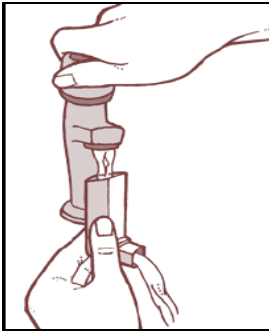
You must keep your inhaler clean, especially the mouthpiece. This will prevent deposits from the aerosol building up.

CLEAN YOUR INHALER AT LEAST ONCE A WEEK.

Take the metal can from the plastic body and rinse the plastic body and cap in warm water. Do not use very hot water to clean your inhaler.

Dry thoroughly (leave to dry overnight if possible) but do not use direct heat.

Put the metal can back in the plastic mouthpiece and replace the cap. Do not put the metal can into water.



Failure to allow the mouthpiece to dry properly will result in an increase in blockage problems.

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 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 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 Beclazone CFC-Free Inhaler 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 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 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, reddening of the skin and hives.
Blurred vision.

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

Hypersensitivity reactions as described above.

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 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 HPRRA 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 CFC-Free Inhaler

Keep out of the sight and reach of children.

Do not use Beclazone CFC-Free Inhaler 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.

The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not pierce the canister. Do not puncture, break or burn the can, even if it seems empty.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Beclazone CFC-Free Inhaler contains

- The active substance is beclometasone dipropionate
Each puff (metered dose) of Beclazone 200 micrograms CFC-Free Inhaler contains 200 micrograms of beclometasone dipropionate.
- The other ingredients are ethanol anhydrous (alcohol) and the propellant norflurane (HFA-134a). This medicine does not contain any CFCs.

Contents of pack

- The name of your medicine is
Beclazone 200 micrograms CFC-Free Inhaler Pressurised Inhalation Solution
Each pack of Beclazone CFC-Free Inhaler contains a single inhaler that supplies 200 metered doses.
- For inhalation use. Pressurised Inhalation, Solution.

Marketing Authorisation Holder and Manufacturer:

Norton Waterford T/A IVAX Pharmaceuticals Ireland
IDA Industrial Estate
Waterford
Ireland.

This leaflet was last revised in August 2023.