

Package leaflet: Information for the patient

Beclazone 50, 100, 250 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, 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 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

Effect

Beclazone CFC-Free Inhaler contains Beclometasone Dipropionate, which belongs to a group of medicines called corticosteroids. Beclometasone dipropionate works on your lungs to help prevent asthma attacks by reducing the swelling and irritation in the walls of the small air passages. This eases your breathing problems. Very little corticosteroid gets absorbed into your body. This medicine is not the same type of steroid used by body-builders and athletes to increase their performance.

Usage

Beclazone CFC-Free Inhalers are used to **prevent** asthma in adults, adolescents and children aged 7 to 12 years. This type of medicine is known as a 'preventer'. You must keep on taking this type of medicine regularly, even when you do not seem to have your asthma symptoms.

Do not use Beclazone CFC-Free Inhalers to relieve an asthma attack, wheezing or breathlessness. You will probably need a different kind of medicine in a different coloured pack for this purpose. You may be using an inhaler that widens your airways during an asthma attack. This type of inhaler is known as a 'reliever'. You can safely use your 'reliever' with your Beclazone CFC-Free Inhaler.

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 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 CFC-Free Inhaler:

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

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.

If you have started to use Beclazone CFC-Free Inhaler with, or instead of, taking steroid tablets you should carry a steroid warning card (if you have one) until your doctor tells you that you no longer need to carry it.

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 or pharmacist if you are taking , have recently taken or might take any other medicines, including medicines obtained without a prescription.

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).

Beclazone CFC-Free Inhaler with food and drink

Beclazone CFC-Free Inhaler should be used as prescribed by your doctor.

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 does not affect the ability to drive or to use machinery.

Beclazone CFC-Free Inhaler contains ethanol

Beclazone 50 micrograms CFC-Free Inhaler:

This medicine contains 2.09 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.

Beclazone 100 micrograms 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.

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

Beclazone 250 micrograms 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 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.

The recommended dose for Beclazone CFC-Free Inhaler is:

Adults and children over 12 years of age

Beclazone 50 micrograms CFC-Free Inhaler: Take one to two puffs twice daily.
Usually the most you would take in 24 hours is sixteen puffs.

Beclazone 100 micrograms 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 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 50 micrograms CFC-Free Inhaler: Take one or two puffs twice daily.
Usually the most you would take in 24 hours is four puffs.

Beclazone 100 micrograms CFC-Free Inhaler: Take one puff twice daily.
Usually the most you would take in 24 hours is two puffs.

Beclazone 250 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.

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.

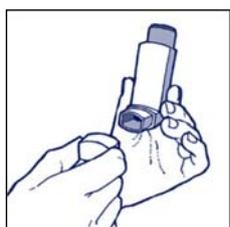
If you find it difficult to use your inhaler with one hand, as shown in the diagrams, use both hands. You must spray your inhaler at the same time as you breathe in.

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

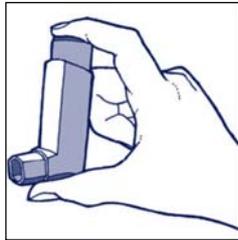
Using the Inhaler

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

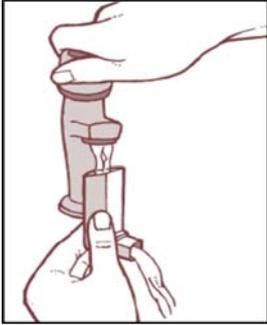
You must keep your inhaler clean, especially the mouthpiece. This will prevent deposits from the aerosol building up.

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

Your dose has been carefully worked out for you. 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 accidentally take more puffs than your doctor has recommended, don't worry. However, if you regularly use more than your recommended dose, you should tell your doctor as soon as possible.

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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor immediately if you experience hypersensitivity (allergic) reactions. These include rash, swelling of the face, eyes, lips and throat and wheezing (because of narrowed airways).

Very common: may affect more than 1 in 10 people

Candidiasis (thrush) in the mouth and throat, which is seen as white spots. Rinsing your mouth with water immediately after using your inhaler will help prevent this from occurring. If you have these symptoms, tell your doctor but do not stop using your inhaler unless your doctor tells you to.

Common: may affect up to 1 in 10 people

Hoarseness and throat irritation.

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

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

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 (see below).

Your doctor will help stop this happening by making sure you use the lowest dose of steroid which controls your symptoms.

Decrease in function of the adrenal gland, which is responsible for producing some hormones that control your body.

Cataracts (formation of a film over the eye lens). Glaucoma (a disease in which the eye pressure increases).

Decreased bone density.

Not known: frequently cannot be estimated from the available data

Blurred vision.

Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable.

Additional side effects in children and adolescents

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

Decrease in growth.

Not known: frequently 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.

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 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 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 50 micrograms CFC-Free Inhaler contains 50 micrograms of beclometasone dipropionate.

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

Each puff (metered dose) of Beclazone 250 micrograms 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 CFC-Free Inhaler looks like and contents of pack

- The name of your medicine is
Beclazone 50 micrograms CFC-Free Inhaler Pressurised Inhalation Solution
Beclazone 100 micrograms CFC-Free Inhaler Pressurised Inhalation Solution
Beclazone 250 micrograms CFC-Free Inhaler Pressurised Inhalation Solution
- Beclazone 50, 250 micrograms CFC-Free Inhaler: Each pack contains a single inhaler that supplies 200 metered doses.
- Beclazone 100 micrograms CFC-Free Inhaler: Each pack contains either a single inhaler, or two inhalers. Each inhaler 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 medicinal product is authorised in the Member States of the EEA under the following names:

Ireland: Beclazone 50/100/250 micrograms CFC-Free Inhaler Pressurised Inhalation Solution
Germany: BeclHexal 100 Mikrogramm Dosieraerosol

This leaflet was last revised in March 2022.