

PATIENT INFORMATION LEAFLET

BECLAZONE® 200 micrograms CFC-FREE INHALER PRESSURISED INHALATION SOLUTION Beclometasone dipropionate

Read all of this leaflet carefully before you start using this medicine.

- 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.

In this leaflet

1. What Beclazone CFC-Free Inhaler is and what it is used for
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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. 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. 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 Beclazone CFC-Free Inhaler.
- If you suffer from or have ever suffered from tuberculosis (TB).

Take special care with Beclazone CFC-Free Inhaler

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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines that you 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).

Taking Beclazone CFC-Free Inhaler with food or drink

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

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Beclazone CFC-Free Inhaler should only be used if recommended by a doctor.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any 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.

3. HOW TO USE BECLAZONE CFC-FREE INHALER

If you use more Beclazone CFC-Free Inhaler than you should:

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.

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

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.

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.

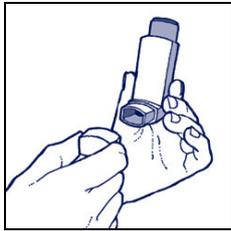
If you find it difficult to use your inhaler with one hand, as shown in the diagrams, use both hands.
You must spray your inhaler at the same time as you breathe in.

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

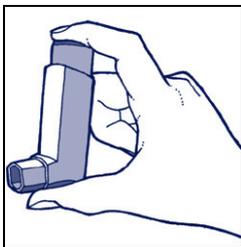
Using the Inhaler

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

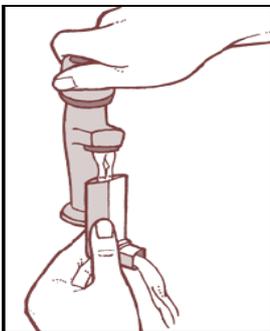
You must keep your inhaler clean, especially the mouthpiece. This will prevent deposits from the aerosol building up.

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 do not take too much. 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 Beclazone CFC-Free Inhaler 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).

Infections and infestations:

Common side effects (affecting more than 1 in 100 and less than 1 in 10 individuals): 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.

Immune system disorders:

Rare side effects (affecting more than 1 in 10,000 and less than 1 in 1,000 individuals): Hypersensitivity reactions as described above.

Respiratory, thoracic and mediastinal disorders:

Common side effects (affecting more than 1 in 100 and less than 1 in 10 individuals): Hoarseness and throat irritation.

Rare side effects (affecting more than 1 in 10,000 and less than 1 in 1,000 individuals): Wheezing, difficulty in breathing or tightness in your chest. If this happens, stop using your inhaler and tell your doctor immediately.

Skin and subcutaneous tissue disorders:

Very rare side effects (affecting less than 1 in 10,000 individuals including isolated reports): Itching, rash and reddening of the skin.

Musculoskeletal and connective tissue disorders:

Very rare side effects (affecting less than 1 in 10,000 individuals including isolated reports): Decreased bone density.

Endocrine disorders:

Very rare side effects (affecting less than 1 in 10,000 individuals including isolated reports): Decrease in function of the adrenal gland, which is responsible for producing some hormones that control your body. Decrease in growth, particularly in children and adolescents.

Eye disorders:

Uncommon side effects (affecting more than 1 in 1,000 and less than 1 in 100 individuals): Blurred vision.

Very rare side effects (affecting less than 1 in 10,000 individuals including isolated reports): Cataracts (formation of a film over the eye lens). Glaucoma (a disease in which the eye pressure increases).

Frequency not known, but may also occur: Central serous retinopathy.

Psychiatric disorders:

Frequency not known, but may also occur:

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 HPRC Pharmacovigilance, Earlsfort Terrace,

IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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. FURTHER 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 September 2017.