

Beclazone CFC-free Inhaler

Beclomethasone Dipropionate (100mcg/actuation)

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WHAT BECLAZONE CFC-FREE INHALER IS USED FOR

Beclazone CFC-Free Inhaler 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.

HOW BECLAZONE CFC-FREE INHALER WORK

Beclazone CFC-Free Inhaler contains Beclomethasone Dipropionate, which belongs to a group of medicines called corticosteroids.

Beclomethasone 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.

BEFORE YOU USE BECLAZONE CFC-FREE INHALER

When you must not use it

- If you are allergic to beclomethasone 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).
- **Do not use** Beclazone CFC-Free Inhalers to relieve an asthma attack, wheezing or breathlessness. 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.

Before you start to use Beclazone CFC-Free Inhaler **Important**

Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. For example Cushing's syndrome, Cushingoid features (eg. facial roundness or puffiness), adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma. Please consult doctor if you experience any of the effects.

It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of inhaled

corticosteroid, if possible, to the lowest dose at which effective control of asthma is maintained. In addition, consideration should be given to referring the patient to a paediatric respiratory specialist. Replacement of systemic steroid treatment with inhaled therapy sometimes unmasks allergies such as allergic rhinitis or eczema previously controlled by the systemic drug.

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.

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:

- barbiturates, phenytoin or rifampicin may enhance the metabolism and reduce the effects of oral corticosteroids.
- Concurrent administration of oral corticosteroids and the potassium-depleting diuretics such as thiazides or frusamide may cause excessive potassium loss. No known interactions have been reported for inhaled beclomethasone dipropionate.

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

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.

**HOW TO USE
BECLAZONE CFC-FREE
INHALER**

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

How much to use

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

The usual dose for Beclazone CFC-Free Inhaler is:

Adults:

Starting dose: 2 puffs, twice a day or 1 puff, three to four times daily.

The maximum recommended dose is 8 puffs a day. The total daily dose may be administered as two, three or four divided doses.

Children

Take one to two puffs twice daily.

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

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.

When to use it

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

How long to use it

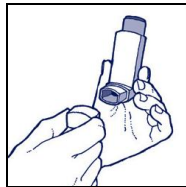
Continue taking Beclazone CFC-Free Inhaler for as long as your doctor recommends.

Instructions for use of the inhaler

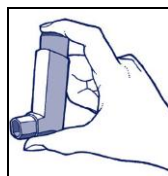
Using the Inhaler

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

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

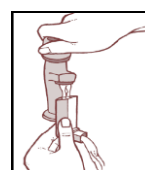
You must keep your inhaler clean, especially the mouthpiece. This will prevent deposits from the aerosol building up.

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 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 take too much (overdose) Beclazone CFC-Free Inhaler.

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.

WHILE YOU ARE USING BECLAZONE CFC-FREE INHALER

Things you must do

Clean your inhaler at least once a week.

Things you must not do

Do not take a double dose to make up for a forgotten dose.

Do not give your inhaler to anyone else. It may harm them even if they seem to have the same symptoms as you have.

Things to be careful of

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.

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.

Inhaled corticosteroids deliver very small amounts of medicine straight to your lungs. Very little corticosteroid is absorbed into the body.

Beclazone CFC-Free inhaler sometimes causes side effects:-

- Wheezing or finding it difficult to breathe because of narrowed airways (bronchospasm).
- A hoarse voice or candidiasis (thrush, seen as white spots) in your mouth and throat. Rinsing mouth with water immediately after using inhaler will help to prevent this.
- Hypersensitivity (allergic) reactions, such as rashes and swelling of your eyes, face, lips and throat.
- Cataracts (a disease of the eye) may occur if you have been using inhaler for a long time, but this side effect is very rare.

If any of the side effects get serious, or if you notice any

side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03- 78835550, or visiting the website portal.bpfk.gov.my (Consumer-> Reporting)

STORAGE AND DISPOSAL OF BECLAZONE CFC-FREE INHALER

Storage

Keep out of the reach and sight of children.

Do not store above 25°C.

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

Disposal

Pressurised aerosol can. Do not puncture, break or burn the can, even if it seems empty.

Do not use this medicine after the expiry date which is stated on the label and carton.

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.

PRODUCT DESCRIPTION

What Beclazone CFC-Free looks like

Each pack of Beclazone CFC-Free Inhaler contains a single inhaler that supplies 200 metered doses.

Aerosol for inhalation, supplied in a pressurised aluminium container.

Ingredient

Active Ingredient

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

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

MAL Number

MAL06011714A

**MANUFACTURER AND
PRODUCT
REGISTRATION HOLDER**

Manufacturer:

IVAX Pharmaceuticals Ireland
IDA Industrial Park
Waterford
Ireland

Product Registration Holder:

Averroes Pharmaceuticals Sdn.
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