

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

##### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using 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.

### **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.

## **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:

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) and adolescents**

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 to two puffs 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.

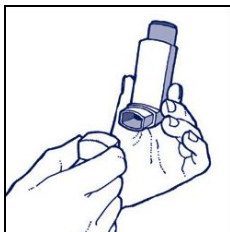
If you find it difficult to use your inhaler with one hand, as shown in the diagrams, use both hands.  
You must spray your inhaler at the same time as you breathe in.

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

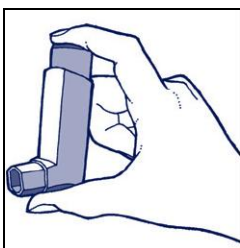
### **Using the Inhaler**

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**

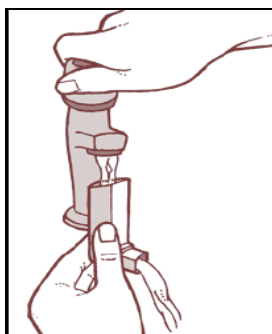
You must keep your inhaler clean, especially the mouthpiece. This will prevent deposits from the aerosol building up.

**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).

**Infections and infestations:**

Common side effects (may affect up to 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.

**Immune system disorders:**

Rare side effects (may affect up to 1 in 1,000 people): Hypersensitivity reactions as described above.

**Respiratory, thoracic and mediastinal disorders:**

Common side effects (may affect up to 1 in 10 people): Hoarseness and throat irritation.

Rare side effects (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.

**Skin and subcutaneous tissue disorders:**

Very rare side effects (may affect up to 1 in 10,000 people including isolated reports): Itching, rash and reddening of the skin.

**Musculoskeletal and connective tissue disorders:**

Very rare side effects (may affect up to 1 in 10,000 people including isolated reports): Decreased bone density.

**Endocrine disorders:**

Very rare side effects (may affect up to 1 in 10,000 people including isolated reports): Decrease in function of the adrenal gland, which is responsible for producing some hormones that control your body.

**Eye disorders:**

Very rare side effects (may affect up to 1 in 10,000 people including isolated reports): Cataracts (formation of a film over the eye lens). Glaucoma (a disease in which the eye pressure increases).

Not known side effects (frequently cannot be estimated from the available data): Blurred vision.

**Psychiatric disorders:**

Not known side effects (frequently cannot be estimated from the available data):

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

### **Additional side effects in children and adolescents**

#### **Endocrine disorders:**

Very rare side effects (may affect up to 1 in 10,000 people including isolated reports): Decrease in growth.

#### **Psychiatric disorders:**

Not known side effects (frequently cannot be estimated from the available data): Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable.

### **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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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 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 05/2017.**