

## NEW ZEALAND CONSUMER MEDICINE INFORMATION

### **Beclazone® 50, 100, 250 micrograms CFC-Free Inhaler** **Beclometasone dipropionate 50, 100, or 250 micrograms per metered dose (“puff”)**

Please read this leaflet carefully before you start using Beclazone CFC-Free Inhaler.

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#### **What is in this leaflet**

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This leaflet answers some common questions about Beclazone CFC-Free Inhaler. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Beclazone CFC-Free Inhaler, against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet. You may need to read it again.**

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#### **What Beclazone CFC-Free Inhaler is used for**

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Beclazone CFC-Free Inhaler is used to help prevent asthma in adults, adolescents and children over 7 years of age. It contains a medicine called beclometasone dipropionate, which belongs to a family of medicines called corticosteroids. Inhaled corticosteroids are not the same as anabolic steroids used by some body-builders and athletes. Your Beclazone CFC-Free Inhaler delivers very small amounts of inhaled corticosteroid straight to your lungs, where it works by reducing inflammation (swelling and irritation) in the small airways. This helps you to breathe easier and helps to prevent asthma attacks. This kind of medicine is known as a ‘Preventer’. It must be used everyday as directed by your doctor even if you have no asthma symptoms.

Beclazone CFC-Free Inhaler may take a few days to start to work. Do not stop using your inhaler unless a doctor tells you to.

Beclazone CFC-Free Inhaler does not give immediate relief from an asthma attack. Do not use Beclazone CFC-Free Inhaler to relieve wheezing or breathlessness - you may have been given a different kind of inhaler medicine, called a ‘Reliever’, for that. Your doctor may have told you to use a Reliever inhaler in addition to your Beclazone CFC-Free Inhaler.

There is no evidence that Beclazone CFC-Free Inhaler is addictive.

Beclazone CFC-Free Inhaler is only available on a doctor's prescription.

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#### **Before you use Beclazone CFC-Free Inhaler**

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##### ***Do not use Beclazone CFC-Free Inhaler if:***

- you have an allergy to beclometasone dipropionate or any of the ingredients listed at the end of this leaflet.
  - the packaging is torn or shows signs of tampering.
  - the expiry date printed on the pack has passed.
- If you take this medicine after the expiry date has passed, it may not work as well.

## ***Before you start to use it***

### **Tell your doctor or your pharmacist if:**

1. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
2. you are pregnant or plan to become pregnant, or if you are breastfeeding or planning to breastfeed. Your doctor will tell you if you should use your inhaler. It is important that asthma is managed well during pregnancy and you should not stop using your inhaler without asking your doctor.
3. you are taking other medicines for your asthma, for example, a Reliever inhaler or other corticosteroids in tablet form. If you have started to use Beclazone CFC-Free Inhaler with or instead of corticosteroid tablets, you should continue to carry your warning card (if you have one) until your doctor tells you not to.
4. you are taking any other medicines, including any that you buy from a pharmacy, supermarket, or health food shop.
5. you currently have an infection. If you use your Beclazone CFC-Free Inhaler while you have an infection, it may hide some of the signs of infection. This may make you think, mistakenly, that you are better or that it is not serious.
6. you suffer from, or have ever suffered from tuberculosis (TB)

Do not use Beclazone CFC-Free Inhaler to treat or relieve an asthma attack.

**If you are not sure whether you should start using Beclazone CFC-Free Inhaler, contact your doctor or pharmacist.**

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## **How to use Beclazone CFC-Free Inhaler**

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You will find detailed instructions on how to use your Beclazone CFC-Free Inhaler in each pack. Read these instructions carefully before you use your inhaler.

**If you are not sure how or when to use your inhaler, ask your doctor or pharmacist. An adult should always help a child with their inhaler. A spacer may be helpful when giving Beclazone CFC-Free Inhaler to young children.** Your doctor, practice nurse or pharmacist will explain what a spacer is and how to use it.

### ***When to use it and how much to use***

Follow your doctor's instructions on when to use your Beclazone CFC-Free inhaler, and on how many puffs to take. The pharmacy label on your Beclazone CFC-Free Inhaler will usually tell you when to use it and how much to use. If you are not sure, ask your doctor or pharmacist.

### ***How long to use it***

Beclazone CFC-Free Inhaler helps control your condition. Therefore you must continue using it everyday, even if you feel better, for as long as your doctor or pharmacist tells you.

### ***How to use it***

You should visit your doctor, practice nurse, or pharmacist regularly to check that you are using your Beclazone CFC-Free Inhaler properly. If you are not using it the right way, the medicine may not be helping you as much as it could.

### **Testing your inhaler**

Before using your Beclazone CFC-Free Inhaler for the first time, remove the plastic mouthpiece cap, shake the inhaler well, and release two puffs into the air to make sure that it works. If it has not been used for several days shake it well and release one puff into the air to make sure that it works.

## Using your inhaler

1. Take the cap off the inhaler mouthpiece. Make sure the mouthpiece is clean and clear 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 about one minute and then start again from step 2. Put the cap back on the inhaler.

## IMPORTANT

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.

If your doctor has given you different instructions for using your inhaler, please follow them carefully. Tell your doctor if you have any problems using Beclazone CFC-Free Inhaler.

Children and people with weak hands may find it easier to hold the inhaler with both hands. In this case for step 2 put your two first fingers on the top of the can and both thumbs on the base of the can.

If you find it difficult to breathe in and use your inhaler at the same time, talk to your doctor or pharmacist. It may be better for you to use a spacer with your Beclazone CFC-Free Inhaler. Your doctor, practice nurse, or pharmacist will explain what a spacer is and how to use it.

### ***In case you take too much (an overdose)***

If you think that you or someone else has used too much of your Beclazone CFC-Free Inhaler, immediately telephone your doctor or the National Poisons Centre (0800 POISON or 0800 764 766), or go to your nearest Accident & Emergency centre. Do this even if there are no signs of poisoning or discomfort.

### ***In case you forget to use it***

If you forget to use your inhaler, do not worry. Take your recommended number of puffs when you remember, then carry on as before. Never use your Beclazone CFC-Free Inhaler more than your doctor has told you to.

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## While you are using Beclazone CFC-Free Inhaler

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### ***Things you must do***

1. If you have an Asthma Action Plan that you have agreed with your doctor, follow it closely at all times.
2. Keep using your Beclazone CFC-Free Inhaler for as long as your doctor or pharmacist tells you.
3. Visit your doctor regularly to check on your asthma condition, and that you are using your inhaler properly.
4. Make sure you keep a Beclazone CFC-Free Inhaler with you at all times.

5. Tell any other doctors, dentists, and pharmacists who are treating you that you are using Beclazone CFC-Free Inhaler.
6. If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using Beclazone CFC-Free Inhaler.
7. If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are using Beclazone CFC-Free Inhaler.
8. If you become pregnant while using Beclazone CFC-Free Inhaler, tell your doctor or pharmacist.

### ***Things you must not do***

1. Your doctor has prescribed Beclazone CFC-Free Inhaler only for you. Do not give this medicine to anyone else, even if they have the same condition as you.
2. Do not use Beclazone CFC-Free Inhaler to treat any other complaints unless your doctor or pharmacist tells you to.
3. Do not stop using Beclazone CFC-Free Inhaler or lower the amount you are using, without checking with your doctor or pharmacist.
4. Do not use Beclazone CFC-Free Inhaler to treat or relieve an asthma attack, wheezing or breathlessness - you may have been given a different kind of inhaler medicine, called a 'Reliever', for that.

### ***Things to be careful for***

Tell your doctor or pharmacist if you notice that you have a sore mouth, throat, or tongue (or notice white spots in your mouth) or a hoarse voice from using Beclazone CFC-Free Inhaler. These side effects are less likely to happen if you rinse your mouth with water after using your Beclazone CFC-Free Inhaler. Do not stop using your inhaler, unless your doctor tells you to.

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## **What if your Beclazone CFC-Free Inhaler doesn't have the usual effect**

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It may take a few days for this medicine to work and reaching full effect within 2-3 weeks. Do not stop using your inhaler unless you are told to by a doctor.

If your asthma condition gets worse, tell your doctor. Your doctor may tell you to take extra puffs of Beclazone CFC-Free Inhaler or add another medicine to your treatment. .

**If your breathing suddenly gets worse just after using your Beclazone CFC-Free Inhaler, tell your doctor or pharmacist immediately.** You may need to use your Reliever inhaler for relief.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Beclazone CFC-Free Inhaler.**

Like all other medicines, Beclazone CFC-Free Inhaler may cause some side effects. If they do occur, most will be minor and short-lived. However, some may be serious and need medical attention. Ask your doctor or pharmacist to answer any questions you may have.

**If you get any of the following side effects and they worry you, tell your doctor or pharmacist but do not stop using your Beclazone CFC-Free Inhaler:**

A sore mouth, throat, or tongue, or a candida infection ('thrush', which looks like white spots) in your mouth and throat, or a hoarse voice. Rinsing your mouth with water immediately after using your inhaler will help to prevent this. Your doctor may tell you to use a treatment for 'thrush' while you keep using your Beclazone CFC-Free Inhaler.

Abdominal pain or vomiting. Treatment with inhaled corticosteroids may affect the normal production of corticosteroids in the body. If you feel unwell, with abdominal pain or vomiting, tell your doctor or pharmacist. This is important if you have had other stresses such as other illnesses, surgery or infection.

Very rarely this medicine may cause anxiety, sleeping problems, depression or feeling worried, restless, nervous, overexcited or irritable (mainly in children).

Very rarely, this medicine may cause allergic reactions including skin rashes or redness, or swelling of the face or throat. **If you have an allergic (hypersensitivity) reaction, you should stop using your inhaler and TELL YOUR DOCTOR IMMEDIATELY.** Symptoms include:

- Swelling of the face, lips, mouth or throat
- Severe skin rash or itching
- Difficulty breathing or swallowing
- Feeling faint or dizzy

Children and adolescents who are using high doses of inhaled corticosteroids for a very long time may grow more slowly than others. Your doctor may wish to check their height regularly.

Contact your doctor if you experience blurred vision or other visual disturbances.

Some people may get other side effects while using Beclazone CFC-Free Inhaler. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## After using Beclazone CFC-Free Inhaler

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### ***Cleaning***

Clean your inhaler at least once a week. It is important to keep your inhaler clean and dry, especially the mouthpiece – this will prevent deposits from building up. It may not work as well if it gets dirty.

### **How to clean your inhaler**

Take the metal can from the plastic body and rinse the plastic body and the cap in warm water. Do not use very hot water to clean your inhaler. Shake off any excess water and allow to air-dry fully. Leave the mouthpiece to dry overnight if possible, but do not use direct heat. Then put the can back in and replace the cap. Do not put the metal can into water. Failure to allow the mouthpiece to dry properly may result in blockage problems.

### ***Storage***

Keep your Beclazone CFC-Free Inhaler in a place where children cannot reach it. Keep your Beclazone CFC-Free Inhaler in a cool dry place where the temperature stays below 25°C. Keep it away from frost, and do not store it in a refrigerator. Keep it away from direct sunlight and heat. Do not leave it in the car on hot days. Do not expose it to temperatures higher than 50°C.

As with most inhalers in metal cans, Beclazone CFC-Free Inhaler may not work as well when the can is very cold. To warm it, pull the metal can out from the plastic body and warm it in your hand for a few minutes. Do not warm the can in any other way. Push the can firmly back into its plastic body before using it again.

### ***Disposal***

If your doctor tells you to stop using Beclazone CFC-Free Inhaler, or the inhaler has passed its expiry date, ask your pharmacist what to do with any inhalers that are left over. The metal can should not be broken, punctured or burnt, even when apparently empty. You can recycle the plastic body and cap along with other household plastics.

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## **Product Description**

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### ***What It Looks Like***

Beclazone CFC-Free Inhaler is a metered-dose aerosol inhaler. The pressurised metal can fits into the plastic mouthpiece body, with a plastic cap.

Beclazone 50 micrograms CFC-Free Inhaler has a cream colour plastic mouthpiece, with a brown colour cap.

Beclazone 100 micrograms CFC-Free Inhaler has a brown colour plastic mouthpiece body, with a white colour cap.

Beclazone 250 micrograms CFC-Free Inhaler has a wine colour plastic mouthpiece body, with a pink colour cap.

### ***Ingredients***

The medicine in your Beclazone CFC-Free Inhaler is called Beclometasone Dipropionate.

Beclazone 50 micrograms CFC-Free Inhaler contains 50 micrograms Beclometasone Dipropionate in each puff.

Beclazone 100 micrograms CFC-Free Inhaler contains 100 micrograms Beclometasone Dipropionate in each puff.

Beclazone 250 micrograms CFC-Free Inhaler contains 250 micrograms Beclometasone Dipropionate in each puff.

Beclazone CFC-Free Inhaler also contains the CFC-free propellant Norflurane (HFA-134a) and Ethanol (Anhydrous).

Beclazone CFC-Free Inhaler does not contain sucrose, lactose, gluten or tartrazine.

Beclazone CFC-Free Inhaler contains at least 200 metered doses.

### ***Sponsor***

Teva Pharma (New Zealand) Limited  
PO Box 128 244  
Remuera  
Auckland, New Zealand.

Beclazone is a trademark.

Do not throw this leaflet away. You may need to read it again.

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