

# BREO ELLIPTA

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using BREO ELLIPTA?

BREO ELLIPTA contains the active ingredients fluticasone furoate and vilanterol trifenate. BREO ELLIPTA is used to treat asthma and chronic obstructive pulmonary disease (COPD)

For more information, see Section [1. Why am I using BREO ELLIPTA?](#) in the full CMI.

### 2. What should I know before I use BREO ELLIPTA?

Do not use if you have ever had an allergic reaction to BREO ELLIPTA or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are**

**breastfeeding. Do not give this medicine to a child under the age of 12 years.**

For more information, see Section [2. What should I know before I use BREO ELLIPTA?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with BREO ELLIPTA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use BREO ELLIPTA?**

- The usual dose is one inhalation once a day. Use BREO ELLIPTA at the same time each day.

More instructions can be found in Section [4. How do I use BREO ELLIPTA?](#) in the full CMI.

### **5. What should I know while using BREO ELLIPTA?**

<b>Things you should do</b>	
	<ul style="list-style-type: none"><li>• Remind any Healthcare Professional (HCP) you visit that you are using BREO ELLIPTA.</li><li>• Contact your doctor if you are concerned about any side effects.</li></ul>

	<ul style="list-style-type: none"> <li>• Tell your doctor immediately, if you become or intend to become pregnant while using BREO ELLIPTA.</li> <li>• Tell your doctor if you feel you are getting breathless or wheezy more often than normal, or if you are using a quick-acting inhaler (such as VENTOLIN/ salbutamol) more than usual.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine suddenly or change the dosage without checking with your doctor.</li> <li>• Do not take any other medicines to help you breathe without checking with your doctor.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>• Be careful driving or operating machinery until you know how BREO ELLIPTA affects you.</li> </ul>

## Looking after your medicine

- Do not open the foil lid until you are ready to use the inhaler for the first time. Once BREO ELLIPTA has been removed from the tray you may store it for a maximum period of 6 weeks or when your counter reads “0”, whichever occurs first.
- Store it in a cool dry place (below 30°C) away from moisture, heat, or sunlight.
- If you store it in the refrigerator, allow the inhaler to return to room temperature at least 1 hour before you use it.

For more information, see Section [5. What should I know while using BREO ELLIPTA?](#) in the full CMI.

## 6. Are there any side effects?

Less serious side effects include fever, headache, changes in taste, tremor, feelings of anxiety, common cold, infection of the nose sinuses or throat, infection of the upper airways, influenza, pain and irritation in the back of the mouth and throat, pressure or pain in the cheeks and forehead, itchy, runny or

blocked nose, cough, hoarseness, bronchitis, joint and back pain, muscle spasms, stomach pain, oral thrush, hyperglycaemia, weakening of the bones, rounded face or slowing of growth in children and adolescents. Serious side effects include allergic reactions, pneumonia, irregular or fast heartbeat, palpitations, blurred vision or eye pain, cataracts or immediate breathing difficulties and wheezing. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# BREO ELLIPTA

**Active ingredients:** *Fluticasone furoate 100 or 200 micrograms and vilanterol trifenate 25 micrograms per inhalation*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using BREO ELLIPTA. **You should also speak to your Healthcare Professional (HCP) if you would like further information or if you have any concerns or questions about using BREO ELLIPTA.**

**Where to find information in this leaflet:**

- [1. Why am I using BREO ELLIPTA?](#)
- [2. What should I know before I use BREO ELLIPTA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use BREO ELLIPTA?](#)
- [5. What should I know while using BREO ELLIPTA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using BREO ELLIPTA?

**BREO ELLIPTA contains the active ingredients fluticasone furoate and vilanterol trifenate.**

Fluticasone furoate belongs to a group of medicines called corticosteroids, often simply called steroids.

Vilanterol trifenate belongs to a group of medicines called bronchodilators.

**BREO ELLIPTA is used to treat asthma and chronic obstructive pulmonary disease (COPD).**

Asthma is a condition affecting the lungs. Symptoms of asthma include shortness of breath, wheezing, chest tightness and cough. Two main causes of asthma symptoms are bronchoconstriction (tightening of the muscle surrounding the airways) and inflammation (swelling and irritation of the airways).

Chronic obstructive pulmonary disease (COPD) is a long-term condition affecting the lungs. Symptoms of COPD include shortness of breath, cough, chest discomfort and coughing up phlegm. The COPD symptoms are mainly due to bronchoconstriction (tightening of the muscle surrounding the airways) and inflammation (swelling and irritation of the airways).

Corticosteroids are used to reduce inflammation. They reduce the swelling and irritation in the small air passages in the lungs and so ease breathing problems. Corticosteroids also help to prevent attacks of asthma.

Bronchodilators relax the muscles of the small air passages in the lungs. This helps to open the airways and makes it easier for air to get in and out of the lungs. When it is used regularly, it helps the small air passages to remain open.

When you use these two medicines together regularly, they will help to control your breathing difficulties.

**BREO ELLIPTA should not be used to relieve a sudden attack of breathlessness or wheezing. If you get this sort of attack, you must use a quick-acting inhaler (such as VENTOLIN).**

Your doctor may have prescribed BREO ELLIPTA for another reason.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

This medicine is not addictive.

This medicine is available only with a prescription.

## **2. What should I know before I use BREO ELLIPTA?**

### **Warnings**

#### **Do not use BREO ELLIPTA if:**

- you are allergic (hypersensitive) to fluticasone furoate, vilanterol, or any of the ingredients listed at the end of this leaflet.
- you are allergic (hypersensitive) to lactose or milk protein.
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

Always check the ingredients to make sure you can use this medicine.



## **Check with your doctor if you:**

- have any other medical conditions.
- take any medicines for any other condition.
- have been diagnosed with an intolerance to some sugars, or to milk protein.
- have liver disease, as you may be more likely to have side effects. If you have moderate or severe liver disease, your doctor will limit your dose to the lower strength of BREO ELLIPTA (100/25 micrograms once daily).
- have heart problems or high blood pressure.
- if you have ever been told you have diabetes or high blood sugar.
- are being treated or have ever been treated for tuberculosis (TB) or pneumonia.
- have eye problems such as glaucoma or cataracts.
- have weak bones (osteoporosis).
- have problems with your thyroid.
- have seizures.
- have any long-standing or untreated infections or have recently been exposed to chickenpox or measles or been around anyone who has chickenpox or measles.
- if you have a problem with your immune system.

Your doctor should give you a personal Action Plan to help manage your asthma or COPD. This plan will include what medicines to take regularly to control your asthma or COPD, as well as what “reliever” medicines to use when you have sudden attacks of breathlessness

or wheezing. Ask your doctor if you have any questions about your Action Plan.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

BREO ELLIPTA is not usually recommended for use during pregnancy. Your doctor will consider the benefit to you and the risk to your baby of using BREO ELLIPTA while you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether the ingredients of BREO ELLIPTA can pass into breast milk.

## **Children and older patients**

- Do not give this medicine to a child under the age of 12 years.
- Safety and effectiveness in children younger than 12 years have not been established.
- BREO ELLIPTA 200/25 micrograms is not recommended in asthma patients aged 75 years and older.

### **3. What if I am taking other medicines?**

Tell your Healthcare Professional (HCP) if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with BREO ELLIPTA and affect how it works or make it more likely that you'll have side effects.**

**These medicines include:**

- ketoconazole, to treat fungal infections.
- ritonavir, to treat viral infections.
- medicines to treat depression or mood/mental disorders (such as monoamine oxidase inhibitors or tricyclic antidepressants).

**Medicines that should be avoided:**

- A class of medicines known as “beta-blockers” used to treat high blood pressure or a heart condition.

Medicines which are similar to BREO ELLIPTA should not be used together as an overdose may result.

**Check with your Healthcare Professional (HCP) if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BREO ELLIPTA.**

## 4. How do I use BREO ELLIPTA?

### How much to use

Always use BREO ELLIPTA exactly as your doctor has told you to. Check with your Healthcare Professional (HCP) if you are not sure.

### Asthma

- The dose for asthma is one inhalation of BREO ELLIPTA 100/25 micrograms once daily OR one inhalation of BREO ELLIPTA 200/25 micrograms once daily, at the same time each day.
- Your doctor will decide which strength of BREO ELLIPTA is required to treat your asthma.

### COPD

- The dose for COPD is one inhalation of BREO ELLIPTA 100/25 micrograms once daily at the same time each day.
- The higher strength of BREO ELLIPTA 200/25 micrograms is not suitable for the treatment of COPD.

### When to use BREO ELLIPTA

- Use BREO ELLIPTA once daily at the same time each day. It is very important that you use BREO ELLIPTA every day, as instructed by your Healthcare Professional (HCP). This will help to keep you free of symptoms throughout the day and night.

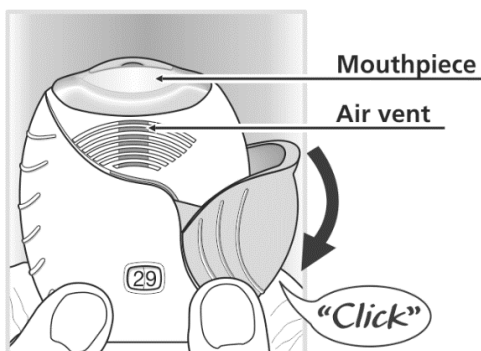
- Use BREO ELLIPTA for as long as your HCP recommends. It will only be effective as long as you are using it. Do not stop unless your HCP advises you to, even if you feel better.

## How to use BREO ELLIPTA inhaler

- To use BREO ELLIPTA, you breathe it into your lungs through your mouth using the ELLIPTA inhaler.
- The full instructions for using BREO ELLIPTA are given on a leaflet inside the pack.
- BREO ELLIPTA is ready to use straight away. No preparation or checks of the inhaler are required.
- Do not open BREO ELLIPTA until you are ready to inhale a dose of medicine.

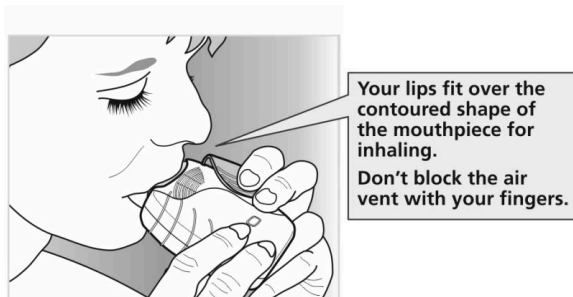
### Step 1: Prepare a dose

- Wait to open the cover until you are ready to take your dose. Slide the cover down until you hear a “click”.
- If the dose counter does not count down as you hear the “click”, the inhaler will not deliver the medicine. Take it back to your pharmacist for advice.
- Do not shake the inhaler at any time.



### Step 2: Inhale your medication

- Whilst holding the inhaler away from your mouth, breathe out as far as is comfortable.
- Do not breathe out into the inhaler.
- Put the mouthpiece between your lips and close your lips firmly around it.
- Do not block the air vent with your fingers.

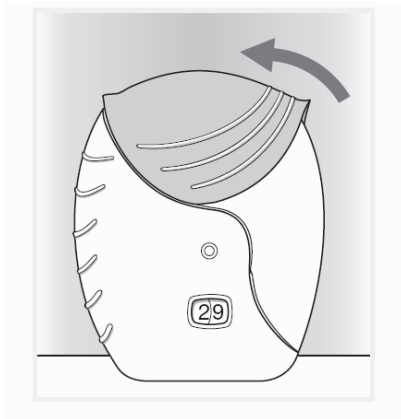


- Take one long, steady, deep breath in. Hold this breath for about 3-4 seconds or as long as is comfortable.
- Remove the inhaler from your mouth.
- Breathe out slowly and gently away from the mouthpiece.
- You may not be able to taste or feel the medicine, even when you are using the inhaler correctly.

After using BREO ELLIPTA, you may clean the mouthpiece using a dry tissue before you close the cover.

### **Step 3: Close the inhaler and rinse your mouth**

- Slide the cover upwards as far as it will go, to cover the mouthpiece.



- Rinse your mouth out with water without swallowing after you have used the inhaler if possible. This will make it less likely that you will develop a sore mouth or throat as side effects.

## **If you forget to use BREO ELLIPTA**

BREO ELLIPTA should be used regularly at the same time each day. If you miss your dose at the usual time, skip the dose you missed and use your next dose when you are meant to. Otherwise, use it as soon as you remember, then go back to using it as you would normally.

**Do not take a double dose to make up for the dose you missed.**

- If you are not sure what to do, ask your Healthcare Professional (HCP).
- If you have trouble remembering to take your medicine, ask your pharmacist for some hints.
- If you become wheezy, or breathless, or develop any other symptoms of an asthma attack, use your quick-acting inhaler (e.g. VENTOLIN/salbutamol) and seek medical advice.

## **If you use too much BREO ELLIPTA (overdose)**

If you think that you have used too much BREO ELLIPTA, you may need urgent medical attention. You may notice that your heart is beating faster than usual, you feel shaky or have a headache.

### **You should immediately:**

- phone the Poisons Information Centre (by calling **13 11 26 in Australia**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

### **You should do this even if there are no signs of discomfort or poisoning.**

If you have used larger doses than instructed for a long period of time, it is particularly important that you ask your Healthcare Professional (HCP) for advice. This is because larger doses of BREO ELLIPTA may reduce the amount of steroid hormones produced naturally by your body.

## **5. What should I know while using BREO ELLIPTA?**

### **Things you should do**

- Remind any Healthcare Professional (HCP) you visit that you are using BREO ELLIPTA, especially if you are about to be started on any new medicine.



- Use BREO ELLIPTA for as long as your doctor recommends. It will only be effective as long as you are using it. Do not stop unless your doctor advises you to, even if you feel better.
- Check with your doctor if you are unsure about which medicines for asthma or COPD you should continue taking whilst being treated with BREO ELLIPTA.
- Continue to use a quick-acting inhaler (VENTOLIN/salbutamol) during an acute episode.
- If you are about to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
- Keep all of your doctor's appointments so that your progress can be checked.

### **Call your doctor straight away if you:**

- experience blurred vision or other visual disturbances.
- experience increased thirst, frequent urination, or unexplained tiredness (signs of high blood sugar).
- become pregnant while taking this medicine.
- feel that your breathing or wheezing gets worse straight after using the BREO ELLIPTA. Stop using it immediately.

Please see Section [6. Are there any side effects?](#) for more instances in which you should contact your doctor.

### **Things you should not do**

- Do not stop using this medicine suddenly or change the dosage without medical advice.

- Do not use BREO ELLIPTA to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not take any other long-acting inhalers which contain inhaled corticosteroids or bronchodilators.
- Do not take any other medicines for your breathing problems without checking with your doctor.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how BREO ELLIPTA affects you.**

This medicine is not expected to affect your ability to drive a car or operate machinery.

## **Action Plan**

If you have an Action Plan for your asthma or COPD that you have agreed with your doctor, follow it closely at all times.

## **Looking after your medicine**

- Store in the original package container in order to protect from moisture and do not open the foil lid until ready to inhale for the first time.
- If you store in a refrigerator allow the inhaler to return to room temperature for at least an hour before use.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 30°C.

**Do not store it:**

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a half metres above the ground is a good place to store the medicines.

**When to discard your medicine**

Ask your pharmacist to safely throw away BREO ELLIPTA one month after you open the foil tray or when the counter reads “0”, whichever comes first. Write the date the inhaler should be discarded on the label in the space provided. The date should be added as soon as the inhaler has been removed from the tray.

**Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

To reduce the chance of side effects, your doctor will prescribe the lowest effective dose of BREO ELLIPTA to control your asthma or COPD.

Do not be alarmed by the following list of side effects. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>General disorders:</b></p> <ul style="list-style-type: none"><li>• high temperature (fever)</li></ul> <p><b>Nervous system disorders:</b></p> <ul style="list-style-type: none"><li>• headache</li><li>• changes in taste</li><li>• tremor</li><li>• feelings of anxiety</li></ul> <p><b>Infections:</b></p> <ul style="list-style-type: none"><li>• common cold</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● infection of the nose sinuses or throat</li> <li>● infection of the upper airways</li> <li>● flu (influenza)</li> </ul> <p><b>Respiratory, thoracic and mediastinal disorders:</b></p> <ul style="list-style-type: none"> <li>● pain and irritation in the back of the mouth and throat</li> <li>● feeling pressure or pain in the cheeks and forehead (may be a sign of inflammation of the sinuses known as sinusitis)</li> <li>● itchy, runny or blocked nose</li> <li>● cough</li> <li>● hoarseness</li> <li>● inflammation of the lungs (bronchitis)</li> </ul> <p><b>Musculoskeletal and connective tissue disorders:</b></p> <ul style="list-style-type: none"> <li>● joint and back pain</li> <li>● muscle spasms</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>Gastrointestinal disorders:</b></p> <ul style="list-style-type: none"> <li>● stomach pain</li> </ul>	
<p><b>Less serious side effects that require medical intervention. Please consult your doctor if you experience any of the following:</b></p> <ul style="list-style-type: none"> <li>● sore, raised patches in the mouth or throat caused by a fungal infection (oral thrush)</li> <li>● increase in blood sugar (hyperglycaemia). This may lead to increased thirst, frequent urination, or unexplained tiredness</li> <li>● you have been told that you have weakening of the bones, leading to risk of fractures</li> <li>● rounded face</li> <li>● slowing of growth in children and adolescents. It is unclear what, if any, difference</li> </ul>	<p><b>Contact your doctor if you experience any of these less serious side effects.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
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## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Allergic reactions:</b></p> <ul style="list-style-type: none"> <li>● If you have any of the following symptoms after using BREO ELLIPTA, stop using this medicine and tell your doctor immediately.</li> <li>● Symptoms of an allergic reaction usually include some or all of the following: <ul style="list-style-type: none"> <li>○ shortness of breath</li> <li>○ wheezing, coughing or difficulty breathing</li> <li>○ swelling of the face, lips/mouth, tongue, or throat</li> <li>○ rash, itching, redness, or hives on the skin</li> <li>○ suddenly feeling weak or light headed (may</li> </ul> </li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>lead to collapse or loss of consciousness)</p> <p><b>Infection of the lungs (pneumonia):</b></p> <ul style="list-style-type: none"> <li>● Symptoms include: <ul style="list-style-type: none"> <li>○ fever</li> <li>○ chills</li> <li>○ increased sputum production</li> <li>○ change in sputum colour</li> <li>○ increased cough</li> <li>○ increased breathing difficulties</li> </ul> </li> </ul> <p><b>Cardiovascular disorders:</b></p> <ul style="list-style-type: none"> <li>● irregular or fast heartbeat</li> <li>● palpitations</li> </ul> <p><b>Eye problems:</b></p> <ul style="list-style-type: none"> <li>● blurred vision or eye pain (possible signs of glaucoma)</li> <li>● cataracts</li> </ul>	



Serious side effects	What to do
<p><b>Immediate breathing difficulties and wheezing:</b></p> <ul style="list-style-type: none"> <li>• If your breathing or wheezing gets worse straight after using BREO ELLIPTA, stop using it immediately, and tell your doctor as soon as possible.</li> </ul>	

**Tell your doctor if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What BREO ELLIPTA contains

<b>Active ingredient</b>	Fluticasone furoate Vilanterol trifenate
<b>Other ingredients</b>	Lactose monohydrate (contains milk protein) Magnesium stearate
<b>Potential allergens</b>	Lactose or milk protein Fluticasone furoate Vilanterol trifenate

Each dose contains 100 or 200 micrograms of the active ingredient fluticasone furoate. The amount depends on which strength of BREO ELLIPTA you have been given. Each dose also contains 25 micrograms of the active ingredient vilanterol.

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What BREO ELLIPTA looks like**

The ELLIPTA device itself is a plastic inhaler with a light grey body, a pale blue mouthpiece cover and a dose counter. It is packaged in a foil laminate tray with a peelable foil lid.

The active substances are in separate blisters in powder form inside the device. There are either 14 or 30 blisters on each strip, and so each device contains either 14 or 30 doses depending on which pack size you have been given.

The tray contains a desiccant sachet, to reduce the moisture in the packaging. Once you have opened the lid of the tray, throw the desiccant away - do not open, eat, or inhale it.

BREO ELLIPTA 200/25 micrograms is AUST R 199747.

BREO ELLIPTA 100/25 micrograms is AUST R 199748.

## **Who distributes BREO ELLIPTA**

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

[www.gsk.com.au/breo](http://www.gsk.com.au/breo)

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