

# Bufomix Easyhaler®

## 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.

### 1. Why am I using Bufomix Easyhaler?

Bufomix Easyhaler contains the active ingredients budesonide and formoterol fumarate dihydrate. Bufomix Easyhaler is used to help prevent breathing problems such as Asthma and Chronic Obstructive Pulmonary Disease (COPD).

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

### 2. What should I know before I use Bufomix Easyhaler?

Do not use if you have ever had an allergic reaction to Bufomix Easyhaler 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.**

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

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

Some medicines may interfere with Bufomix Easyhaler 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 Bufomix Easyhaler?

- Use Bufomix Easyhaler every day as directed by your doctor. This will make sure that it works properly in controlling your asthma or COPD.

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

### 5. What should I know while using Bufomix Easyhaler?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, surgeon, anaesthetist or pharmacist you visit that you are using Bufomix Easyhaler.</li><li>• Rinse your mouth after using Bufomix Easyhaler</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Bufomix Easyhaler is unlikely to affect your ability to drive or use machinery but you should be careful until you know how Bufomix Easyhaler affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store Bufomix Easyhaler below 25°C and protect from moisture.</li><li>• Keep the inhaler in the foil bag until you are ready to start using it</li><li>• Place the inhaler in the protective cover provided after you take it out of the foil bag.</li></ul>

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

### 6. Are there any side effects?

Common side effects include sore, yellowish, raised patches in the mouth (thrush); shakiness; headache and rapid heartbeat. Tell your doctor if you notice you feel more wheezy, your chest may feel tight more often or you have increased coughing or breathing problems.

Some side effects can only be found when your doctor does tests from time to time to check your progress.

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.

# Bufomix Easyhaler®

Active ingredients: *Budesonide and Formoterol fumarate dihydrate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Bufomix Easyhaler. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Bufomix Easyhaler.**

Where to find information in this leaflet:

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

## 1. Why am I using Bufomix Easyhaler?

Bufomix Easyhaler contains two active ingredients, **budesonide and formoterol (as formoterol fumarate dihydrate)**.

- Budesonide is a corticosteroid which reduces swelling and irritation in the lungs.
- Formoterol belongs to a group of medicines called 'long acting beta-2 agonists' or 'bronchodilators'. Bronchodilators help the airways in the lungs to stay open. This makes it easier for air to get in and out to help you breathe more easily. The effects last for up to 12 hours

Bufomix Easyhaler is used to help prevent breathing problems such as:

- Asthma
- Chronic Obstructive Pulmonary Disease (COPD)

Bufomix Easyhaler can be used by some people with asthma to treat the symptoms when their asthma gets worse and to prevent asthma attacks or symptoms from happening.

Bufomix Easyhaler also helps to prevent breathlessness and wheeziness in people who need regular treatment.

## 2. What should I know before I use Bufomix Easyhaler?

### Warnings

**Do not use Bufomix Easyhaler if:**

- you are allergic to budesonide, formoterol fumarate dihydrate, or any of the ingredients listed at the end of this leaflet.

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

**If you have breathing difficulties or wheezing that get worse straight after using Bufomix Easyhaler stop using your Bufomix Easyhaler inhaler.** Use your fast-acting 'reliever' inhaler to help your breathing and **tell your doctor straight away.**

**Check with your doctor if you:**

- have or have had any other medical conditions especially the following:
  - thrush in your mouth
  - tuberculosis
  - diabetes
  - a thyroid condition
  - high blood pressure
  - heart problems including an irregular or fast heartbeat
  - liver problems
  - low levels of potassium in your blood
- take any medicines for any other condition

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.

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

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

Tell your doctor or pharmacist 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 Bufomix Easyhaler and affect how it works.**

Tell your doctor about any other medicines you are taking especially the following:

- Beta-blockers (such as atenolol, metoprolol, propranolol) used to treat high blood pressure and other heart conditions
- Ketoconazole, a medicine used to treat fungal infections.
- Medicines used to treat irregular heartbeats such as disopyramide, procainamide and quinidine
- Medicines used to treat depression or other mood/mental disorders such as tricyclic antidepressants, monoamine oxidase inhibitors and phenothiazines

- Medicines used to treat hayfever, coughs, colds and runny nose such as antihistamines
- Diuretics (sometimes called fluid tablets) that are used to treat high blood pressure and heart problems
- Xanthine derivatives (such as theophylline) which are a class of medicines used to treat asthma and COPD
- Any other steroid medicines (taken by mouth or as an injection) used to treat swelling, inflammation or breathing problems.

These medicines may be affected by Bufomix Easyhaler or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Bufomix Easyhaler.**

## 4. How do I use Bufomix Easyhaler?

### How much to use

Follow the instructions provided by your doctor about how to use Bufomix Easyhaler.

Do not exceed the recommended dose. Check with your doctor or pharmacist if you are not sure.

Bufomix Easyhaler is not recommended for use in children below 12 years of age.

#### For Asthma

Your doctor will prescribe Bufomix Easyhaler for you to use as either:

- an anti-inflammatory reliever medicine only,
- both an anti-inflammatory reliever and a daily maintenance preventer medicine; or,
- as a daily maintenance preventer only, where another medicine is used as a reliever.

#### **Anti-inflammatory reliever medicine (Bufomix Easyhaler 200/6)**

##### **Adults and children over 12 years**

- When you get asthma symptoms, take 1 inhalation and wait a few minutes. If you do not feel better, take another inhalation.
- If you use Bufomix Easyhaler to help stop asthma symptoms from happening (for example, just before exercise or before you get exposed to other things that cause symptoms), your doctor will tell you how many inhalations to take.
- **Do not use more than 6 inhalations on a single occasion or more than 12 inhalations in any day.**
- **If your symptoms continue to get worse over 3 days, despite using your inhaler, tell your doctor.**
- Always keep your Bufomix Easyhaler reliever with you.

#### **Anti-inflammatory reliever and a daily maintenance preventer medicine (Bufomix Easyhaler 200/6)**

##### **Adults and children over 12 years**

- Your doctor may tell you to use Bufomix Easyhaler every day to help prevent asthma symptoms. This is called a 'maintenance' dose'.

- The usual maintenance dose is 2 inhalations per day of Bufomix Easyhaler 200/6. This is taken as either 1 inhalation in the morning and evening or as 2 inhalations in the morning or evening. Depending on your Asthma doctor may tell you to use 2 inhalations twice a day of Bufomix Easyhaler 200/6.
- When you get asthma symptoms, take 1 inhalation of Bufomix Easyhaler 200/6 and wait a few minutes. If you do not feel better, take another inhalation.
- If you also use Bufomix Easyhaler to help stop asthma symptoms from happening, just before exercise or before you get exposed to other things that cause symptoms, your doctor will tell you how many inhalations to take.
- **Do not use more than 6 inhalations on a single occasion or more than 12 inhalations in any day.**
- **If your symptoms continue to get worse over 3 days, despite using your inhaler, tell your doctor.**
- Always keep your Bufomix Easyhaler reliever with you.

#### **Daily fixed dose maintenance therapy (Bufomix Easyhaler 200/6 and 400/12)**

- **For adults and children over 12 years**, the usual maintenance dose is 1 or 2 inhalations per day of Bufomix Easyhaler 200/6 taken twice a day.
- **Patients over 18 years** who need a higher dose can take up to 2 inhalations of Bufomix Easyhaler 400/12 twice a day.
- Use Bufomix Easyhaler every day as directed by your doctor. This will make sure that it works properly in controlling your asthma or COPD.
- Do not take more than 2 inhalations twice a day of 200/6 or 400/12.
- Your doctor will tell you what dose to take. You should use Bufomix Easyhaler every day to help control your asthma.
- Always keep your separate reliever medicine with you.

#### **For Chronic Obstructive Pulmonary Disease (COPD)**

##### **Adults**

- 2 inhalations of Bufomix Easyhaler 200/6 twice daily or
- 1 inhalation of Bufomix Easyhaler 400/12 twice daily.
- Use Bufomix Easyhaler every day as directed by your doctor. This will make sure that it works properly in controlling your COPD.

#### **When to use Bufomix Easyhaler**

- Your doctor will tell you how to use Bufomix Easyhaler depending on you condition and the best way to control your asthma or COPD.

**If your asthma or breathing gets worse tell your doctor straight away.** You may feel more wheezy, your chest may feel tight more often or you may need to use more of your fast acting 'reliever' medicine. This may mean your chest condition is getting worse and you could become seriously ill. If any of these happen, you should continue to take Bufomix Easyhaler and see your doctor as you may need additional treatment.

## How to use Bufomix Easyhaler

Bufomix Easyhaler is for inhalation through the mouth only.

Bufomix Easyhaler is easy to use. Read through these instructions first: they tell you what you should do and what to look out for.

### Unpack the inhaler

Take the inhaler out of its packaging. It comes in a laminate pouch to keep the powder dry. Only take it out of the pouch when you are ready to start using it.

The inhaler should come with a dust cap on the mouthpiece (**Figure 1**). The carton will also include a protective cover.

**Figure 1**



After removal from the laminate pouch, you must fit the inhaler into its protective cover which helps improve the durability of the product.

To fit the inhaler into the protective cover, open up the protective cover (**Figure 2a**). Ensure the dustcap (dark purple/blue cap) covers the mouthpiece of inhaler (this stops the inhaler going off by accident) before inserting the inhaler into the protective cover. Close the protective cover until you hear a click to ensure tight seal.

The inhaler should remain inside the protective cover at all times until dosing. (**Figure 2b**)

Discard the inhaler after 4 months after removal from the laminate pouch. The inhaler label includes a space for you to write the date when you should discard the inhaler.

**Figure 2a**



**Figure 2b**



## How to take a dose from Bufomix Easyhaler

### 1. Shake

- Remove the dust cap.
- Hold the inhaler upright, gripping it between your finger and thumb
- Shake the device vigorously up and down three to five times. This is to make sure the powder flows properly and gives the correct dose (**Figure 3**).
- Make sure you shake it up and down and you do not click it while you shake it.

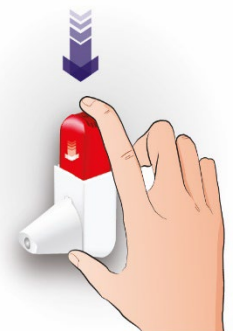
**Figure 3**



### 2. Click

- Make sure the dust cap is not on the inhaler, it will stop you clicking it.
- Still holding the inhaler upright, squeeze until you hear a click, and let it click back again. This delivers powder into the inhalation channel inside the mouthpiece (**Figure 4**).
- Only click down once, just before you take the medicine. If you click it more than once, see section "If you have problems using the inhaler".
- Make sure you keep the inhaler upright as you click it and inhale the dose.

**Figure 4**



### 3. Inhale

In the sitting or standing position

- Breathe out normally
- Place the mouthpiece in your mouth between your teeth and close your lips tightly around the mouthpiece to make a good seal (**Figure 5**).
- Make sure the whole mouthpiece is well inside your mouth, so the powder does not go on your teeth
- Take a strong and deep breath in
- Take the inhaler out of your mouth and, then breathe out gently away from the inhaler.
- Do not breathe out into the inhaler. This is important: it could clog up the inhaler. If you breathed out into the inhaler, see section "If you have problems using the inhaler"

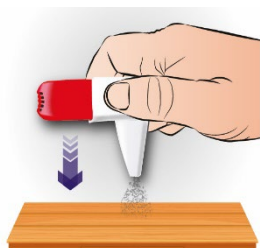
**Figure 5**



### If you have problems using the inhaler

- Do not rush things. It is important to breathe normally. Practice a few times, in front of the mirror if this helps.
- If you click the inhaler by accident, or if you might have clicked it more than once, or if you breathe out into it, tap the mouthpiece to empty the powder onto a table top, or the palm of your hand (**Figure 6**). This ensures proper dosing. Then start again with steps 1, 2 and 3.

**Figure 6**



### If you are to take a second inhalation

- Start again with steps 1, 2 and 3 (Note that you need to shake the device again as instructed in step 1).

### After you have used the inhaler

- Put the dust cap back on the mouthpiece and close the protective cover.
- Rinse your mouth with water and spit it out after you use Bufoimix Easyhaler.

### Cleaning the Easyhaler

- Clean the Easyhaler's mouthpiece at least once a week with a dry cloth. Do not use water: the powder in the Easyhaler is sensitive to moisture. You can take the Easyhaler out of the protective cover to wipe it. When you are putting it back into its protective cover, put the dust cap on the mouthpiece to stop it going off accidentally.

### Getting a new Easyhaler

- The inhaler has a dose counter which shows how many doses are left. The counter turns after every fifth actuation (**Figure 7**). When the numbers go red, there are 20 doses left. If you do not already have a new Easyhaler, contact your doctor for a new prescription. When the counter reaches 0, you need to replace the Easyhaler.

**Figure 7**



For more information on how to use Bufoimix Easyhaler please visit [www.orionpharma.com.au/patient](http://www.orionpharma.com.au/patient).

### If you forget to use Bufoimix Easyhaler

Bufoimix Easyhaler should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

- If you become wheezy or feel tight in the chest before the next dose is due, use a 'reliever inhaler' in the usual way. You should get relief from your 'reliever inhaler' within a few minutes.

If you are not sure what to do, ask your doctor or pharmacist.

### If you use too much Bufoimix Easyhaler

If you think that you have used too much Bufoimix Easyhaler, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), 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.

The most common symptoms that may occur if you use too much Bufoimix Easyhaler are trembling, headache, breathing faster than usual a rapid heartbeat or increased levels of blood sugar.

## 5. What should I know while using Bufoimix Easyhaler?

### Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Bufoimix Easyhaler.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

- It may affect other medicines used during surgery.
- It is important that all doctors treating you are aware that you are on inhaled steroids. If your body is stressed by, for example, severe infection, surgical operation, an accident etc, you may need steroid tablets or injections for a time.

### Rinse your mouth after using Bufoimix Easyhaler

- Some people find that their mouth, throat or tongue becomes sore or that their voice becomes hoarse after inhaling this medicine. It may be helpful to rinse your mouth with water and spit it out after using your Bufoimix Easyhaler. Tell your doctor but do not stop treatment unless told to do so.

### Call your doctor straight away if you:

- experience a change in your vision

### Things you should not do

- Do not stop using this medicine suddenly. If you stop using it suddenly, your condition may worsen, or you may have unwanted side effects. Check with your doctor before you stop using this medicine. If possible,

your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

## Driving or using machines

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

## Looking after your medicine

- Store Bufomix Easyhaler below 25°C and protect from moisture.
- Keep the inhaler in the foil bag until you are ready to start using it.
- Place the inhaler in the protective cover when you take it out of the foil bag.

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; for example, 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.**

## When to discard your medicine

Replace your Bufomix Easyhaler inhaler 4 months after first opening the foil bag.

If your Bufomix Easyhaler gets damp, you need to replace it with a new one.

## 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.

## 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.

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

### Allergic reactions:

You may notice **your breathing suddenly gets worse** after using Bufomix Easyhaler. You may be very wheezy and cough. You may also notice itching and swelling (usually of the face, lips, tongue, or throat). **If you get these effects or if they happen suddenly after using Bufomix Easyhaler, tell your doctor straight away or go to Accident and Emergency at your nearest hospital.**

### Common Side Effects

- sore, yellowish, raised patches in the mouth (thrush)
- soreness in the mouth, throat, or tongue
- hoarseness
- headache
- shakiness
- pains in joints

- increase in heart rate

Pneumonia (lung infection) has been reported commonly in patients with COPD. Tell your doctor if you notice any of the following symptoms:

- increase in sputum production
- change in sputum colour
- fever, chills
- increased cough and increased breathing problems.

### Uncommon Side Effects

- skin rash
- shortness of breath
- sweating, trembling, feeling
- nervous or anxious
- weight gain
- changes in vision
- sleep disturbances
- muscle cramps
- dizziness

### Rare Side Effects

- behavioural changes, including unusual activity and irritability
- rounded face
- bruising
- slowing of growth in children and adolescents
- irregular heartbeat
- chest pain

The above list includes very serious side effects that may need urgent medical attention or hospitalisation.

**Some side effects can only be found when your doctor does tests from time to time to check your progress, for example:**

- increases in blood sugar (glucose) levels
- changes in blood pressure
- loss of bone density
- reduced potassium levels in the blood
- changes in the function of the adrenal glands, which make the body's own steroids

**Tell your doctor or pharmacist 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 or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What Bufomix Easyhaler contains

Active ingredients	Metered dose	Delivered dose
<b>(main ingredients)</b>	200 or 400 micrograms budesonide and 6 or 12 micrograms formoterol fumarate dihydrate*	160 or 320 micrograms budesonide and 4.5 or 9 micrograms formoterol fumarate dihydrate*
<b>Other ingredients (inactive ingredients)</b>	Lactose monohydrate	
<b>Potential allergens</b>	Lactose monohydrate Milk proteins	

\*abbreviated to *formoterol* for ease of reference

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

### What Bufomix Easyhaler looks like

Bufomix Easyhaler is a dry powder inhaler device that contains a white to yellowish powder. Each Easyhaler multiple dose powder inhaler is individually sealed in a foil bag and is provided in a carton together with a protective cover.

Bufomix Easyhaler 200/6 (AUST R 338159): 1 inhaler per carton, each inhaler contains 60 or 120 inhalations.\*

Bufomix Easyhaler 400/12 (AUST R 338160): 1 inhaler per carton, each inhaler contains 60 inhalations.

\*Not all pack sizes may be marketed.

### Who distributes Bufomix Easyhaler

Orion Pharma (Aus) Pty Limited  
Level 24, Tower 3  
300 Barangaroo Avenue, Sydney, NSW 2000, Australia  
Telephone: 1800 861 913

This leaflet was prepared in July 2025.