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Package leaflet: Information for the patient

Bufomix Easyhaler, 160 micrograms/4.5 micrograms/inhalation, Inhalation Powder Budesonide/formoterol fumarate dihydrate

Read all of this leaflet carefully before you start taking 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Bufomix Easyhaler 160/4.5 is and what it is used for
2. What you need to know before you use Bufomix Easyhaler 160/4.5
3. How to use Bufomix Easyhaler 160/4.5
4. Possible side effects
5. How to store Bufomix Easyhaler 160/4.5
6. Contents of the pack and other information

1. What Bufomix Easyhaler 160/4.5 is and what it is used for

Bufomix Easyhaler is an inhaler that is used to treat asthma in adults and adolescents aged 12 - 17 years. It is also used to treat the symptoms of Chronic Obstructive Pulmonary Disease (COPD) in adults aged 18 years and older. It contains two different medicines: budesonide and formoterol fumarate dihydrate.

- Budesonide belongs to a group of medicines called ‘corticosteroids’. It works by reducing and preventing swelling and inflammation in your lungs.
- Formoterol fumarate dihydrate belongs to a group of medicines called ‘long-acting beta₂ adrenoceptor agonists’ or ‘bronchodilators’. It works by relaxing the muscles in your airways. This helps you to breathe more easily.

Asthma

Bufomix Easyhaler 160/4.5 can be prescribed for asthma in two different ways.

a) Some people are prescribed two asthma inhalers: Bufomix Easyhaler 160/4.5 and a separate ‘reliever inhaler’.

- They use Bufomix Easyhaler every day. This helps to prevent asthma symptoms from happening.

- They use their ‘reliever inhaler’ when they get asthma symptoms, to make it easier to breathe again.

b) Some people are prescribed Bufomix Easyhaler 160/4.5 as their only asthma inhaler.

- They use Bufomix Easyhaler every day. This helps to prevent asthma symptoms from happening.
- They also use Bufomix Easyhaler when they need extra doses for relief of asthma symptoms, to make it easier to breathe again and if agreed with the doctor also to prevent asthma symptoms from happening (for example, when exercising or on exposure to allergens). They do not need a separate inhaler for this.

Chronic obstructive pulmonary disease (COPD)

Bufomix Easyhaler 160/4.5 can also be used to treat the symptoms of COPD in adults. COPD is a long-term disease of the airways in the lungs, which is often caused by cigarette smoking.

2. What you need to know before you use Bufomix Easyhaler 160/4.5

Do not use Bufomix Easyhaler 160/4.5:

- if you are allergic to budesonide, formoterol or to the other ingredient of this medicine (listed in section 6) which is lactose (which contains small amounts of milk protein).

Warnings and precautions

Talk to your doctor or pharmacist before using Bufomix Easyhaler if you:

- are diabetic
- have a lung infection
- have high blood pressure or you have ever had a heart problem (including an uneven heart beat, a very fast pulse, narrowing of the arteries or heart failure)
- have problems with your thyroid or adrenal glands
- have low levels of potassium in your blood
- have severe liver problems.

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

Rinse your mouth after inhaling your dose in order to avoid fungal infection in the mouth.

Other medicines and Bufomix Easyhaler

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Some medicines may increase the effects of Bufomix Easyhaler and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Beta-blocker medicines (such as atenolol or propranolol for high blood pressure), including eyedrops (such as timolol for glaucoma).
- Medicines for a fast or uneven heart beat (such as quinidine).
- Medicines like digoxin, often used to treat heart failure.
- Diuretics, also known as ‘water tablets’ (such as furosemide). These are used to treat high blood pressure.
- Steroid medicines that you take by mouth (such as prednisolone).
- Xanthine medicines (such as theophylline or aminophylline). These are often used to treat asthma.
- Other bronchodilators (such as salbutamol).
- Tricyclic anti-depressants (such as amitriptyline) and the anti-depressant nefazodone.
- Phenothiazine medicines (such as chlorpromazine and prochlorperazine).
- Medicines to treat infections (such as ketoconazole, itraconazole, voriconazole, posaconazole, clarithromycin and telithromycin).
- Medicines for Parkinson’s disease (such as levo-dopa).
- Medicines for thyroid problems (such as levo-thyroxine).

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before using Bufomix Easyhaler.

Also tell your doctor or pharmacist if you are going to have a general anaesthetic for an operation or for dental work.

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 using this medicine.
- Do not use Bufomix Easyhaler unless your doctor tells you to.
- If you get pregnant while using Bufomix Easyhaler, do not stop using Bufomix Easyhaler but talk to your doctor immediately.

Driving and using machines

Bufomix Easyhaler has no or negligible effect on your ability to drive or to use tools or machines.

Bufomix Easyhaler contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before using this medicine. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant. The excipient lactose contains small amounts of milk proteins, which may cause allergic reaction.

3. How to use Bufomix Easyhaler 160/4.5

- Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- It is important to use Bufomix Easyhaler every day, even if you have no asthma or COPD symptoms at the time.
- Your doctor will want to regularly check your asthma symptoms.

If you have been taking steroid tablets for your asthma or COPD, your doctor may reduce the number of tablets that you take, once you start to use Bufomix Easyhaler. If you have been taking oral steroid tablets for a long time, your doctor may want you to have blood tests from time to time. When reducing oral steroid tablets, you may feel generally unwell even though your chest symptoms may be improving. You might experience symptoms such as a stuffy or runny nose, weakness or joint or muscle pain and rash (eczema). If any of these symptoms bother you, or if symptoms such as headache, tiredness, nausea (feeling sick) or vomiting (being sick) occur, please contact your doctor immediately. You may need to take other medication if you develop allergic or arthritic symptoms. Speak to your doctor if you are concerned as to whether you should continue to use Bufomix Easyhaler.

Your doctor may consider adding steroid tablets to your usual treatment during periods of stress (for example, when you have a chest infection or before an operation).

Important information about your asthma or COPD symptoms

If you feel you are getting breathless or wheezy while using Bufomix Easyhaler, you should continue to use Bufomix Easyhaler but go to see your doctor as soon as possible, as you may need additional treatment.

Contact your doctor immediately if:

- your breathing is getting worse or you often wake up at night with asthma.
- your chest starts to feel tight in the morning or your chest tightness lasts longer than usual.

These signs could mean that your asthma or COPD is not being properly controlled and you may need different or additional treatment immediately.

ASTHMA

Bufomix Easyhaler 160/4.5 can be prescribed for asthma in two different ways. The amount of Bufomix Easyhaler to use and when to use it depends on how it has been prescribed for you.

- a) If you have been prescribed Bufomix Easyhaler and a separate reliever inhaler, read the section called 'A) Using Bufomix Easyhaler and a separate reliever inhaler'.
- b) If you have been prescribed Bufomix Easyhaler as your only inhaler, read the section called 'B) Using Bufomix Easyhaler as your only asthma inhaler'.

A) Using Bufomix Easyhaler and a separate reliever inhaler

Use your Bufomix Easyhaler every day. This helps to prevent asthma symptoms from happening.

Adults (18 years and above)

- The usual dose is 1 or 2 inhalations, twice a day.
- Your doctor may increase this to 4 inhalations, twice a day.
- If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.

Adolescents (12 to 17 years)

- The usual dose is 1 or 2 inhalations, twice a day.
- If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.

A lower strength of Bufomix Easyhaler is available for children aged from 6 to 11 years.

Bufomix Easyhaler is not recommended to be used in children who are younger than 6 years.

Your doctor (or asthma nurse) will help you to manage your asthma. They will adjust the dose of this medicine to the lowest dose that controls your asthma. However, do not adjust the dose without talking to your doctor (or asthma nurse) first.

Use your separate 'reliever inhaler' to treat asthma symptoms when they happen. Always keep your 'reliever inhaler' with you to use when you need it. Do not use Bufomix Easyhaler to treat asthma symptoms - use your reliever inhaler.

B) Using Bufomix Easyhaler as your only asthma inhaler

Only use Bufomix Easyhaler in this way if your doctor has told you to and if you are aged 12 or above.

Use your Bufomix Easyhaler 160/4.5 every day. This helps to prevent asthma symptoms from happening. You can take:

- 1 inhalation in the morning **and** 1 inhalation in the evening
- or**
- 2 inhalations in the morning
- or**
- 2 inhalations in the evening.

Your doctor may increase this to 2 inhalations twice a day.

Also use Bufomix Easyhaler 160/4.5 as a 'reliever inhaler' to treat asthma symptoms when they happen and to prevent asthma symptoms from happening (for example, when exercising or on exposure to allergens).

- If you get asthma symptoms, take 1 inhalation and wait a few minutes.
- If you do not feel better, take another inhalation.
- Do not take more than 6 inhalations at a single time.

Always keep your Bufomix Easyhaler with you, so you can use it when you need it.

A total daily dose of more than 8 inhalations is not normally needed. However, your doctor may allow you to take up to 12 inhalations a day for a limited period.

If you regularly need to use 8 or more inhalations a day, make an appointment to see your doctor or nurse. They may need to change your treatment.

Do not use more than 12 inhalations in total in 24 hours.

If you are doing exercise and you get asthma symptoms, use Bufomix Easyhaler as described here. It is important that you discuss with your doctor the use of Bufomix Easyhaler to prevent asthma symptoms from happening; how often you exercise or how often you are exposed to allergens could impact the treatment that it is prescribed to you.

COPD (Chronic Obstructive Pulmonary Disease)

- Only to be used by adults (aged 18 years and above).
- The usual dose is 2 inhalations twice a day.

Your doctor may also prescribe other bronchodilator drugs, for example anticholinergics (such as tiotropium or ipratropium bromide) for your COPD disease.

If you use more Bufomix Easyhaler than you should

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not exceed your prescribed dose without seeking medical advice.

The most common symptoms that may occur after if you use more Bufomix Easyhaler 160/4.5 than you should are trembling, headache or a rapid heart beat.

If you forget to use Bufomix Easyhaler

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Do **not** take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

The instructions how to use the inhaler are at the end of the leaflet.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If either of the following happen to you, stop using Bufomix Easyhaler and talk to your doctor immediately:

- Swelling of your face, particularly around your mouth (tongue and/or throat and/or difficulty to swallow) or hives together with difficulties to breath (angioedema) and/or sudden feeling of faintness. This may mean that you are having an allergic reaction. This happens rarely, may affect up to 1 in 1,000 people.
- Sudden acute wheezing or shortness of breath immediately after using your inhaler. **If either of these symptoms occur, stop using your Bufomix Easyhaler inhaler straightaway and use your 'reliever' inhaler. Contact your doctor immediately as you may need to have your treatment changed.** This happens very rarely, may affect up to 1 in 10,000 people.

Tell your doctor if you have any of the following while taking Bufomix Easyhaler as they could be symptoms of a lung infection:

- fever or chills,
- increased mucus production, change in mucus colour,
- increased cough or increased breathing difficulties.

Pneumonia (infection of the lung) in COPD patients is a common side effect (may affect up to 1 in 10 people).

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Palpitations (awareness of your heart beating), trembling or shaking. If these effects occur, they are usually mild and usually disappear as you continue to use Bufomix Easyhaler.
- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using your Bufomix Easyhaler.
- Mild sore throat, coughing and a hoarse voice.
- Headache.

Uncommon (may affect up to 1 in 100 people)

- Feeling restless, nervous or agitated.
- Disturbed sleep.
- Feeling dizzy.
- Nausea (feeling sick).
- Fast heart beat.
- Bruising of the skin.
- Muscle cramps.
- Blurred vision.

Rare (may affect up to 1 in 1,000 people)

- Rash, itching.
- Bronchospasm (tightening of the muscles in the airways which causes wheezing). If the wheezing comes on suddenly after using Bufomix Easyhaler stop using Bufomix Easyhaler and talk to your doctor immediately.
- Low levels of potassium in your blood.
- Uneven heart beat.

Very rare (may affect up to 1 in 10,000 people)

- Depression.
- Changes in behaviour, especially in children.
- Chest pain or tightness in the chest (angina pectoris).
- An increase in the amount of sugar (glucose) in your blood.
- Taste changes, such as an unpleasant taste in the mouth.
- Changes in your blood pressure.

Inhaled corticosteroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. The effects include:

- changes in bone mineral density (thinning of the bones)
- cataract (clouding of the lens in the eye)
- glaucoma (increased pressure in the eye)
- a slowing of the rate of growth of children and adolescents
- an effect on the adrenal gland (a small gland next to the kidney).

These effects are much less likely to happen with inhaled corticosteroids than with corticosteroid tablets.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA website: www.hpra.ie or email: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Bufomix Easyhaler 160/4.5

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date that is stated on the carton, foil bag and label of your inhaler after EXP. The expiry date refers to the last day of that month.

- After opening the foil bag do not store above 25°C and store protected from moisture. It is recommended to keep the Easyhaler in its protective cover.
- If your Bufomix Easyhaler gets damp you need to replace it with a new one.
- Replace Bufomix Easyhaler 4 months after you opened the foil bag. Write down the date you opened the bag to help you remember.
- 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 Bufomix Easyhaler 160/4.5 contains

- The active substances are budesonide and formoterol fumarate dihydrate. Each inhaled dose contains 160 micrograms of budesonide and 4.5 micrograms of formoterol fumarate dihydrate.
- The other ingredient is lactose monohydrate (which contains milk proteins).

What Bufomix Easyhaler 160/4.5 looks like and contents of the pack

Bufomix Easyhaler 160/4.5 is an inhaler containing your medicine. The inhalation powder is white to yellowish in colour. Each inhaler contains 60 or 120 doses and has a white body with red upper part. Bufomix Easyhaler 160/4.5 is available in packs of 1 or 3 inhaler(s), 120 doses also in pack of 2 inhalers. Not all pack sizes may be marketed.

Your pack may contain a protective cover. If you need a protective cover, please contact the Marketing Authorisation Holder (details given below).

Marketing Authorisation Holder

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer

Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Orion Pharma (Ireland) Limited, c/o Allphar Services Ltd, 4045 Kingswood Road, Citywest Business Park, Co Dublin.

This leaflet was last revised in March 2022.

Detailed and updated information on how to use this product is available by scanning this QR code (included also on outer carton and inhaler label) with a smartphone. The same information is also available on the following URL: www.oeh.fi/bfie.

QR code to www.oeh.fi/bfie.

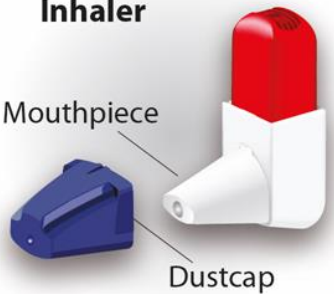
How to use the Easyhaler inhaler

About your Easyhaler


Bufomix Easyhaler may be different to inhalers you have used in the past. Therefore it is very important that you use it properly as using incorrectly can lead to you not receiving the right amount of medicine. This could make you very unwell or could lead to your asthma and COPD not being treated as it should.


Your doctor, nurse or pharmacist will show you how to use your inhaler properly. Make sure you understand the correct way to use the inhaler. If you are unsure contact your doctor, nurse or pharmacist. As with all inhalers, caregivers should ensure that children prescribed Bufomix Easyhaler use correct inhalation technique, as described below. You can also use the instruction video at www.oeh.fi/bfie


When you first get your Easyhaler

<p>The Easyhaler comes in a foil bag. Do not open the foil bag until you are ready to start using the medicine as it helps to keep the powder dry in the inhaler.</p> <p>When you are ready to start treatment open the bag and record the date e.g., in your calendar.</p> <p>Use the inhaler within 4 months of removing from the foil bag.</p>	<p style="text-align: center;">Inhaler</p> 
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HOW TO USE CORRECTLY

<p>Step 1: SHAKE</p> <ul style="list-style-type: none">• Remove the dustcap• Shake the inhaler 3 to 5 times holding it in the upright position	<p>SHAKE x 3-5</p> 	<p>Important points to remember</p> <ul style="list-style-type: none">• It is important to keep the inhaler in the upright position• If you accidentally click while you shake the inhaler, empty the powder from the mouthpiece as shown below
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<p>Step 2: CLICK</p> <ul style="list-style-type: none"> • Keep holding the inhaler upright between your forefinger and thumb • Press down until you hear a click, and let the inhaler click back again. This releases a dose • Only click down once 	<p>CLICK x 1</p> 	<p>Important points to remember</p> <ul style="list-style-type: none"> • The inhaler will not click if the dustcap is still on • Only click down once • If you accidentally click more than once, empty the powder from the mouthpiece, see below • Click to release dose before you inhale, not at the same time • Keep the inhaler upright when you click it and when you inhale the dose. If you tip it, the powder could fall out before you are able to inhale it
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<p>Step 3: INHALE</p> <ul style="list-style-type: none"> • Keep holding the inhaler upright • Breathe out normally • Place the mouthpiece in your mouth between your teeth and close your lips tightly around the mouthpiece • Take a strong and deep breath in • Take the inhaler out of your mouth, then breathe out normally. 	<p>INHALE</p> 	<p>Important points to remember</p> <ul style="list-style-type: none"> • Make sure the whole mouthpiece is well inside your mouth, so that the medication gets into your lungs • Make sure your lips make a good seal around the mouthpiece • Do not breathe out into the inhaler. This is important: it could clog up the inhaler. If you breathed out into the inhaler, empty the powder from mouthpiece, see below
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If you need to take another inhalation, please repeat the steps 1-3 Shake-Click-Inhale.

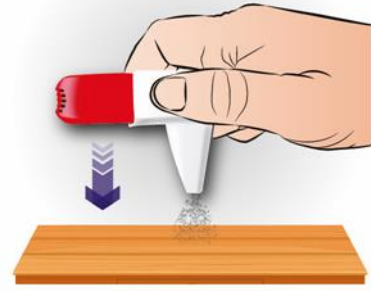
After you have used the inhaler:

- Put the dust cap back on the mouthpiece. It stops the inhaler going off by accident.
- After you have taken the dose, rinse your mouth with water, and spit it out.

How to empty the powder from the mouthpiece

If you click the inhaler by accident, or if you might have clicked it more than once, or if you breathe out into it, empty the mouthpiece.

- Tap the mouthpiece to empty the powder onto a table top, or the palm of your hand.
- Then start again with steps Shake-Click-Inhale.



Cleaning the Easyhaler

Keep your inhaler dry and clean. If necessary you may wipe the mouthpiece of your inhaler with a dry cloth or tissue. Do not use water: the powder in the Easyhaler is sensitive to moisture.

Using the Easyhaler with a protective cover

You may use a protective cover with your inhaler. This helps to improve durability of the product. When you first insert your inhaler in the protective cover make sure the dustcap is on the inhaler as this stops it going off by accident. You can use the inhaler without removing it from the protective cover.

Follow the same instructions as above, **1. Shake – 2. Click – 3. Inhale.**

Remember to:

- Keep the inhaler in the upright position when clicking it
- Replace the dustcap after taking the dose as this stops the inhaler going off by accident.



When to switch to a new Easyhaler

The dose counter shows the number of remaining doses. The counter turns after every 5th click. When the dose counter starts turning 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 (zero), you need to replace the Easyhaler.

If you use the protective cover, you can keep it and insert your new inhaler into it.



Remember

- **1. Shake – 2. Click – 3. Inhale.**
- After you have taken the dose, rinse your mouth with water and spit it out.
- Do not get your inhaler wet, protect it from moisture.

If you have any further questions on the use of this product, ask your doctor or pharmacist.