

Package leaflet: Information for the patient

Bufar Easyhaler, 80 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 Bufar Easyhaler 80/4.5 is and what it is used for
2. What you need to know before you use Bufar Easyhaler 80/4.5
3. How to use Bufar Easyhaler 80/4.5
4. Possible side effects
5. How to store Bufar Easyhaler 80/4.5
6. Contents of the pack and other information

1. What Bufar Easyhaler 80/4.5 is and what it is used for

Bufar Easyhaler is an inhaler that is used to treat asthma in adults, adolescents and children aged 6 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.

This medicine is not suitable for people with severe asthma. It can be prescribed for asthma in two different ways.

a) Some people are prescribed two asthma inhalers: Bufar Easyhaler 80/4.5 and a separate ‘reliever inhaler’

- They use Bufar 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 Bufar Easyhaler 80/4.5 as their only asthma inhaler

- They use Bufar Easyhaler every day. This helps to prevent asthma symptoms from happening.
- They also use Bufar Easyhaler when they need extra doses for relief of asthma symptoms, to make it easier to breathe again. They do not need a separate inhaler for this.

2. What you need to know before you use Bufar Easyhaler 80/4.5

Do not use Bufar Easyhaler 80/4.5:

- 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 Bufar 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 Bufar 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 Bufar 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 leva-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 Bufar 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 Bufar Easyhaler unless your doctor tells you to.
- If you get pregnant while using Bufar Easyhaler, do not stop using Bufar Easyhaler but talk to your doctor immediately.

Driving and using machines

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

Bufar 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 Bufar Easyhaler 80/4.5

- 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 Bufar Easyhaler every day, even if you have no asthma symptoms at the time.
- Your doctor will want to regularly check your asthma symptoms.

If you have been taking steroid tablets for your asthma, your doctor may reduce the number of tablets that you take, once you start to use Bufar 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 Bufar 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 symptoms

If you feel you are getting breathless or wheezy while using Bufar Easyhaler, you should continue to use Bufar 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 is not being properly controlled and you may need different or additional treatment immediately.

ASTHMA

Bufar Easyhaler 80/4.5 can be prescribed for asthma in two different ways. The amount of Bufar Easyhaler to use and when to use it depends on how it has been prescribed for you.

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

A) Using Bufar Easyhaler and a separate reliever inhaler

Use your Bufar 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.

Children (6 to 11 years)

- The usual dose is 2 inhalations, twice a day.

Bufar Easyhaler 80/4.5 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 Bufar Easyhaler to treat asthma symptoms - use your reliever inhaler.

B) Using Bufar Easyhaler as your only asthma inhaler

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

Use your Bufar Easyhaler 80/4.5 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.

Also use Bufar Easyhaler 80/4.5 as a ‘reliever inhaler’ to treat asthma symptoms when they happen.

- 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 Bufar 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 Bufar Easyhaler as described here. However, do not use Bufar Easyhaler just before exercise to stop asthma symptoms from happening.

Preparing your new Bufar Easyhaler

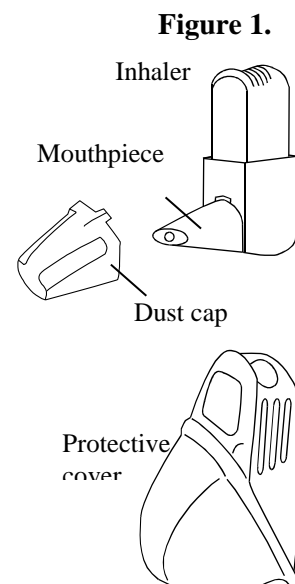
Bufar Easyhaler is easy to use. Read through these instructions first: they tell you what you should do and what to look out for.

UNPACK THE INHALER

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

Make sure you have all the parts (Figure 1):

- An inhaler, with a dust cap on the mouthpiece
- Possibly a protective cover.

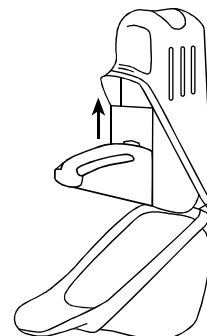


If you don't use a protective cover move on to section "To take a dose from Bufar Easyhaler".

Fit the inhaler into its protective cover:

Open up the protective cover (Figure 2). Make sure the dust cap covers the mouthpiece of the inhaler (this stops the inhaler going off by accident). Insert the inhaler into the protective cover to improve durability of the product. If you are not using the device immediately, close the protective cover.

Figure 2.



TO TAKE A DOSE FROM BUFAR EASYHALER

If you use a protective cover with your Bufar Easyhaler, open it.

Remove the dust cap.

A. Shake

- Shake the device vigorously up and down three to five times (Figure 3a or 3b). This is to make sure the powder flows properly and gives the correct dose.

Figure 3a.

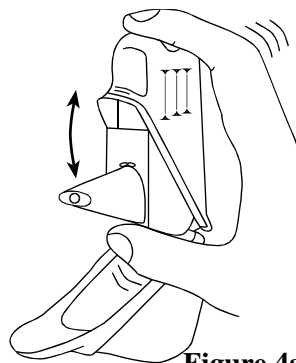
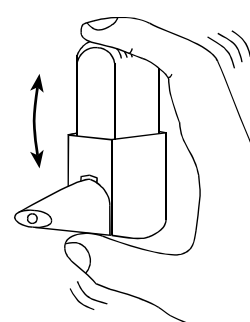


Figure 3b.



Make sure...

- you shake it up and down
- you don't click it while you shake it.

Figure 4a.

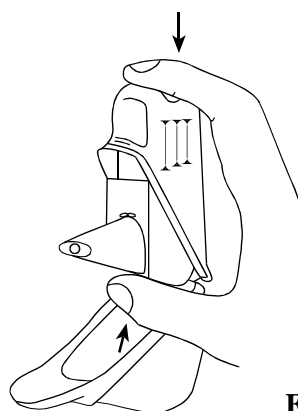
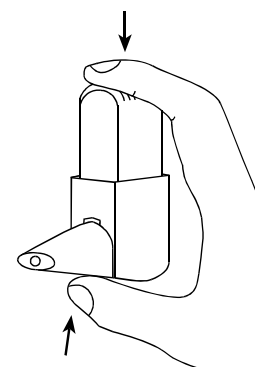


Figure 4b.



B. Click

- Hold the inhaler upright, gripping it between your finger and thumb (Figure 4a or 4b).
- Squeeze until you hear a click, and let it click back again. This delivers powder into the inhalation channel inside the mouthpiece.

Make sure...

- the dust cap is not on the inhaler, it will stop you clicking it.
- you 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".
- you keep the inhaler upright as you click it and inhale the dose.

Figure 5a.

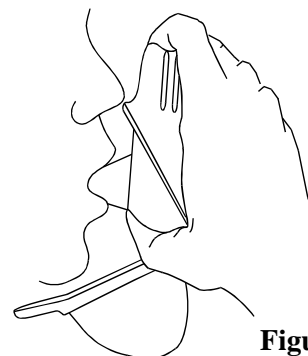


Figure 5b.

C. Inhale

In the sitting or standing position

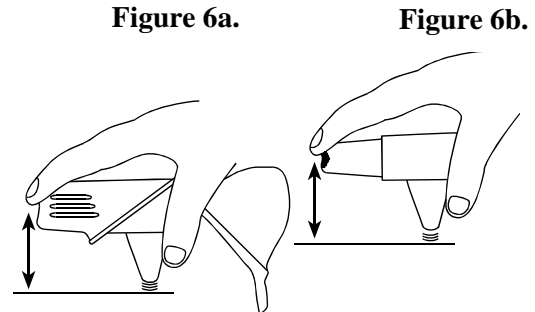
- Breathe out normally
- Place the mouthpiece in your mouth between your teeth and close your lips tightly around the mouthpiece
- Take a strong and deep breath in (Figure 5a or 5b)
- Take the inhaler out of your mouth, then breathe normally away from the inhaler.

Make sure...

- the whole mouthpiece is well inside your mouth, so the powder doesn't go on your teeth
- your lips make a good seal around the mouthpiece
- you don't 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".

If you have problems using the inhaler

- Don't rush things. It's 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 6a or 6b). This ensures proper dosing. Then start again with steps A, B and C.



If you're to take a second inhalation

- Start again with steps A, B and C (Note that you need to shake the device again).

After you've used the inhaler

- Put the dust cap back on the mouthpiece. If you are using a protective cover, close it.
- Rinse your mouth with water after your daily morning and/or evening doses, and spit it out.

As with all inhalers, caregivers should ensure that children prescribed Bufar Easyhaler use correct inhalation technique, as described above.

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.

If you use a protective cover, you can take the Easyhaler out of it 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 (Figure 7a or 7b). The counter turns after every fifth actuation. When the dose counter starts turning red, there are 20 doses left. If you don't already have a new Easyhaler, contact your doctor for a new prescription. When the counter reaches 0, you need to replace the Easyhaler even though you can still observe the powder in the clear window on the back of the inhaler.

- Take the old Easyhaler out of its protective cover (if you are using one).
- Keep the protective cover and dispose of the old inhaler (see section 5 *How to store Bufar Easyhaler*).
- Take the new inhaler out of the bag. Insert the new inhaler into the protective cover (if you use one), with the dust cap on.

Now you can use the new inhaler as usual. See section 3 for more details.

Figure 7a.

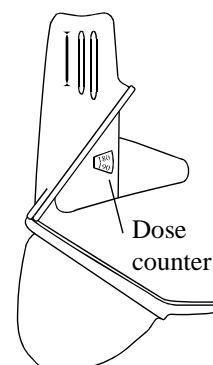
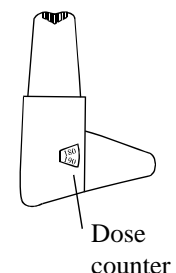


Figure 7b.



If you use more Bufar 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 Bufar Easyhaler 80/4.5 than you should are trembling, headache or a rapid heart beat.

If you forget to use Bufar 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.

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 Bufar 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, affecting less than 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 Bufar 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, affecting less than 1 in 10,000 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 Bufar Easyhaler.
- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using your Bufar 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 Bufar Easyhaler stop using Bufar 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bufar Easyhaler 80/4.5

- 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, bag and label of your inhaler after EXP. The expiry date refers to the last day of that month.
- After opening the laminate 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 Bufar Easyhaler gets damp you need to replace it with a new one.
- Replace Bufar Easyhaler 4 months after you opened the laminate bag. Write down the date you opened the bag here 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 Bufar Easyhaler 80/4.5 contains

- The active substances are budesonide and formoterol fumarate dihydrate. Each inhaled dose contains 80 micrograms of budesonide and 4.5 micrograms of formoterol fumarate dihydrate.
- The other ingredient is lactose monohydrate (which contains milk proteins).

What Bufar Easyhaler 80/4.5 looks like and contents of the pack

Bufar Easyhaler 80/4.5 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.

Bufar Easyhaler 80/4.5 is available in packs of 1 or 3 inhaler(s).

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

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