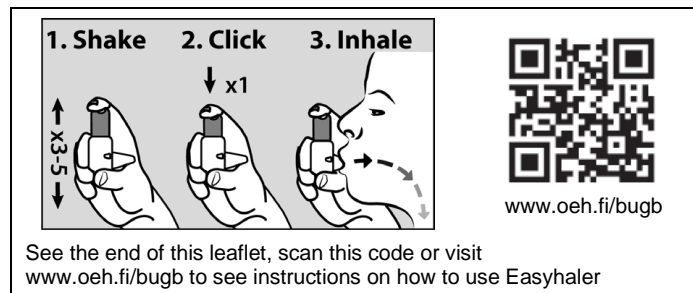


## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Easyhaler® Budesonide 400 micrograms/dose inhalation powder (budesonide)



### Read all of this leaflet carefully before you start using 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 or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- The name of your medicine is Easyhaler Budesonide 400 micrograms/dose inhalation powder but it will be referred to as Easyhaler Budesonide throughout the remainder of this leaflet.
- This medicine is also available in other strengths.

### What is in this leaflet:

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

## 1. WHAT EASYHALER BUDESONIDE IS AND WHAT IT IS USED FOR

The active ingredient in Easyhaler Budesonide is budesonide. Budesonide powder is packed in an inhaler. You inhale the powder into your lungs through the mouthpiece of the inhaler. Budesonide works by reducing and preventing swelling and inflammation in your lungs.

Easyhaler Budesonide is a medicine called “**preventer**”. It is used to prevent symptoms of asthma. It belongs to a group of medicines called corticosteroids.

Budesonide will NOT stop an asthma attack that has already started. Therefore you always need to have a fast acting bronchodilating “**reliever**” (a beta<sub>2</sub>-agonist) with you.

The effect of budesonide may be noticeable after a few days treatments but will only reach its maximum after a few weeks. You should use Easyhaler Budesonide regularly to prevent the asthmatic inflammation. Go on taking this medicine regularly according to instructions, even if you don't have any symptoms.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU USE EASYHALER BUDESONIDE

### Do not use Easyhaler Budesonide, if you are allergic:

- to budesonide
- to the other ingredient of this medicine (listed in section 6) which is lactose (which contains small amounts of milk protein).

Contact your doctor so that your medicine can be changed to another.

### Warnings and Precautions

Tell your doctor **before** you use Easyhaler Budesonide, if you have:

- pulmonary tuberculosis
- any untreated bacteria, virus or fungal infections in your mouth, airways or lungs
- severe liver disease.

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.

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

### Other medicines and Easyhaler Budesonide

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

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

Tell your doctor, if you are using:

- nasal medicines containing corticosteroids
- corticosteroid tablets
- itraconazol or ketoconazol containing antifungal medicines.

### 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 for advice before taking this medicine. It is important for both foetus and mother to maintain an adequate asthma treatment during pregnancy. As with other drugs administered during pregnancy, the benefit of the administration of budesonide for the mother should be weighed against the risks to the foetus. The lowest effective dose of budesonide needed to maintain adequate asthma control should be used.

### Driving and using machines

Easyhaler Budesonide is not known to affect your ability to drive or operate machinery.

**Easyhaler Budesonide inhalation powder contains a small amount of lactose**, which probably does not cause problems even if you have lactose intolerance. If you have been told by your doctor that you have intolerance to some sugars, talk to your doctor before using this medicine.

Lactose contains small amounts of milk proteins, which may cause allergic reaction.

## 3. HOW TO USE EASYHALER BUDESONIDE

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacies if you are not sure.

Your doctor has prescribed a suitable strength and dose for you. Follow your doctor's instructions carefully.

Replacing corticosteroid tablets with Easyhaler Budesonide:

Tell your doctor, if you use corticosteroid tablets (e.g. cortisone tablets) to treat your asthma. Your doctor may ask you to gradually reduce the number of tablets and finally stop the treatment within a few weeks. If you feel unwell during this transfer period, contact your doctor, but do not stop using Easyhaler Budesonide.

### Use in adults (including the elderly) and adolescents (12 to 17 years):

- 1–2 doses inhaled in the mornings and in the evenings or once a day in the evenings.

### Use in children 6 to 11 years:

- 1–2 doses inhaled in the mornings and in the evenings or once a day in the evenings.

While the treatment continues your doctor may from time to time adjust the dose to find the **lowest** dose needed to control your asthma (the maintenance dose).

If Easyhaler Budesonide is to be used by your child, make sure that he/she can use it correctly.

In addition to the preventer, Easyhaler Budesonide, you also need a bronchodilating reliever:

Budesonide will NOT stop an asthma attack that has already started. Therefore you always need to have a fast acting bronchodilating **reliever** (a beta<sub>2</sub>-agonist) with you in case of acute symptoms of asthma.

If you regularly use a reliever inhaler (beta<sub>2</sub>-agonist), you should inhale it before Easyhaler Budesonide (preventer).

### Worsening of the asthma symptoms during the treatment:

Contact your doctor as soon as possible, if:

- your wheezing or chest tightness gets worse during the treatment
- you need to use your reliever inhaler more often than before
- your reliever inhaler doesn't help as well as before your asthma may be getting worse and you may need an extra treatment.

### If you use more Easyhaler Budesonide than you should

If you have taken a larger dose or more doses than you were told to, tell your doctor as soon as possible. You should continue to use Easyhaler Budesonide unless your doctor tells you otherwise.

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

### If you forget to use Easyhaler Budesonide

If you have missed a dose, take one as soon as possible, or you can just take the next dose when it is due. It is best to take your medicine at the same time each day.

Do not take a double dose to make up for a forgotten dose.

### If you stop using Easyhaler Budesonide

Do not stop using Easyhaler Budesonide without consulting your doctor. If you stop using this medicine abruptly, it may make your asthma worse.

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

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

## 4. POSSIBLE SIDE EFFECTS

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

Common (may affect up to 1 in 10 people):

Irritation in throat, swallowing difficulties, cough and fungal infection (thrush) in mouth or throat. If you get any of these side effects, do not stop taking Easyhaler Budesonide. Talk to your doctor.

You can help to prevent the above-mentioned side effects by rinsing your mouth and throat with water or brushing your teeth after every time you have taken a dose. Do not swallow the rinsing water, spit it out.

Uncommon (may affect up to 1 in 100 people):

Anxiety, depression, cataract, blurred vision, muscle spasm and tremor.

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

Too much or too little cortisol in blood. Underactive adrenal gland (gland next to kidneys). Skin rash, itching, bruising, hoarseness, restlessness and nervousness. Growth retardation in children. Behavioural changes especially in children.

### Rare serious allergic reaction:

If itching, rash, reddened skin, swelling of the eye lids, lips, face or throat, wheezing, low blood pressure or collapse appear shortly after taking a dose, act in the following way:

- stop taking Easyhaler Budesonide
- seek medical advice immediately.

### Shortness of breath immediately after dosing:

Rarely, inhaled drugs can cause an increase in wheezing and shortness of breath (bronchospasm) immediately after dosing. If this occurs:

- stop taking Easyhaler Budesonide
- take fast acting bronchodilating reliever
- seek medical advice immediately.

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

Glaucoma. Decrease in bone mineral density (weakening of the bones).

Not known (frequency cannot be estimated from the available data):

Sleeping problems, aggressiveness, increased motor activity (difficulty to stay still) and irritable. These effects are more likely to occur in children.

If you think you might have any of these rare side effects, or if you are worried about the possibility of them, talk to your doctor.

### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE EASYHALER BUDESONIDE

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the label and on the carton after 'EXP'. The expiry date refers to the last day of that month.
- Before the first use: store in unopened foil bag.
- After opening the foil bag: store below 30°C protected from moisture. It is recommended to keep the Easyhaler in its protective cover.
- Replace Easyhaler Budesonide with a new at the latest 6 months after you opened the foil bag. Write down the date you opened the bag to help you remember.
- If your Easyhaler Budesonide gets damp, you need to replace it with a new one.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### What Easyhaler Budesonide contains

The active substance is budesonide.

One metered dose contains: budesonide 400 micrograms.

The other ingredient is lactose monohydrate (which contains milk protein).

### What Easyhaler Budesonide looks like and contents of the pack

White or almost white powder.

Easyhaler Budesonide 400 micrograms/dose inhalation powder contains 100 doses and protective cover.

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/bugb](http://www.oeh.fi/bugb)



Manufactured by Orion Corporation, Orion Pharma, Orionintie 1, 02200 Espoo, Finland.

Procured from within the EU. Repackaged by the Product Licence Holder: MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall, WS9 8ER.

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PL: 33532/1534

Leaflet dated 20<sup>th</sup> December 2023

Leaflet coded MPT1534L1

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## HOW TO USE THE EASYHALER INHALER

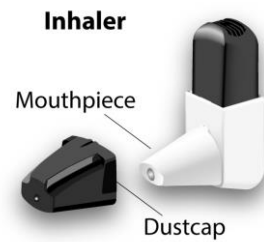
### About your Easyhaler

Easyhaler Budesonide 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 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 Easyhaler Budesonide use correct inhalation technique, as described below. You can also use the instruction video at [www.oeh.fi/bugb](http://www.oeh.fi/bugb).

### When you first get your Easyhaler

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.



When you are ready to start treatment open the bag and record the date e.g., in your calendar.

Use the inhaler within 6 months of removing from the foil bag.

## HOW TO USE CORRECTLY

### Step 1: SHAKE

- Remove the dustcap
- Shake the inhaler **3 to 5** times holding it in the **upright position**



### Important points to remember

- 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

### Step 2: CLICK

- 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**



### Important points to remember

- 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

### Step 3: INHALE

- 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, hold breath **for at least 5 seconds**, then breathe out normally.



### Important points to remember

- 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

If you need to take another inhalation, please repeat the steps 1-3 **Shake-Click-Inhale**.

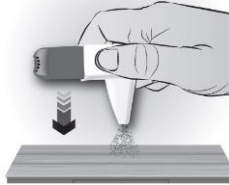
### After you have used the inhaler:

- 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 and/or brush your teeth. This may help to stop you getting thrush and becoming hoarse.

### 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 and/or brush your teeth.
- 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.