

Scan this code or visit www.oeh.fi/uk to see instructions on how to use Easyhaler

Package leaflet: Information for the user

Easyhaler Budesonide 100 micrograms/dose
Easyhaler Budesonide 200 micrograms/dose
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.

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 beta₂-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

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 or have recently taken 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

Ask your doctor for advice before using Easyhaler Budesonide, if you are pregnant, planning to become pregnant or if you are breastfeeding. 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 medicinal product.

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

3. How to use Easyhaler Budesonide

See “Instructions for using your Easyhaler” at the end of this leaflet.

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 beta₂-agonist) with you in case of acute symptoms of asthma.

If you regularly use a reliever inhaler (beta₂-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.

4. Possible side effects

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

Common side effects (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 side effects (may affect up to 1 in 100 people)

Anxiety, depression, cataract, muscle spasm and tremor.

Rare side effects (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 side effects (may affect up to 1 in 10,000 people)

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

Frequency not known, but may also occur:

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

5. How to store Easyhaler Budesonide

Keep this medicine out of the sight and reach of children.

Before the first use: store in unopened laminate pouch.

After opening the laminate pouch: 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 laminate pouch. Write down the date you opened the pouch to help you remember: _____

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

Do not use this medicine after the expiry date which is stated on the label and carton.

Do not throw away any medicines via 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 Easyhaler Budesonide contains

- The active substance is budesonide
- 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 100 microg/dose and 200 microg/dose inhalation powder

- 200 doses + protective cover
- 200 doses
- 2 x 200 doses

Easyhaler Budesonide 400 microg/dose inhalation powder

- 100 doses + protective cover
- 100 doses
- 2 x 100 doses

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer

Orion Corporation, Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

This medicinal product is authorised in the Member States of the EEA under the following names:

Finland, Hungary, Germany	Budesonid Easyhaler
Spain	Budesonida Easyhaler
Belgium, Poland	Budesonide Easyhaler
Netherlands	Budesonide Orion Easyhaler
United Kingdom	Easyhaler Budesonide
Slovenia	Budesonid Orion Easyhaler
Norway, Sweden, Denmark, Czech Republic, Slovakia, Austria, Estonia, Lithuania, Latvia	Giona Easyhaler

This leaflet was last revised in 11/2016

INSTRUCTIONS FOR USING YOUR EASYHALER

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

UNPACKING THE EASYHALER

The Easyhaler (Figure 1) comes in a laminate pouch to keep the powder dry. **Do not open the pouch until you are ready to start using your Easyhaler.**

A protective cover is optional. **If you do not use the protective cover**, move on to section “Taking a dose from Easyhaler Budesonide” (See Figures b).

Open the protective cover and insert the Easyhaler into it (Figure 2). Make sure the dust cap covers the mouthpiece of the Easyhaler (this stops the Easyhaler going off by accident).

If you are not using the Easyhaler immediately, close the protective cover.

TAKING A DOSE FROM EASYHALER BUDESONIDE

If you are also using a “reliever” inhaler, use it first.

Open the protective cover, if you are using it.

Remove the dust cap.

A. Shake

Shake the Easyhaler vigorously up and down three to five times (Figure 3a or 3b), to allow proper powder flow and a correct dose. After shaking, hold the Easyhaler in the **upright** position.

B. Click

Press the Easyhaler **once** between your finger and thumb until you hear a click (Figure 4a or 4b), and let it click back again, to deliver powder into the inhalation channel inside the mouthpiece. Keep holding the Easyhaler in the upright position.

If you think that you have clicked the Easyhaler more than once, see section NOTE! (Figure 6a or 6b).

Figure 1.

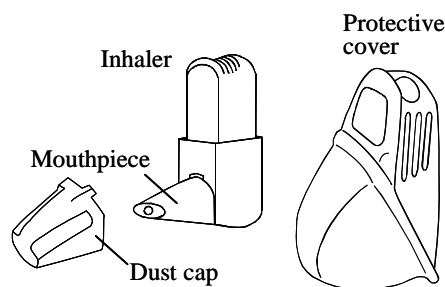


Figure 2.

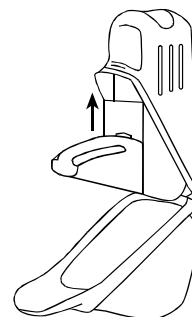


Figure 3a.

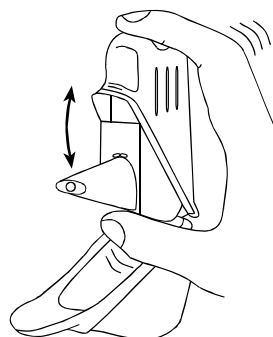


Figure 3b.

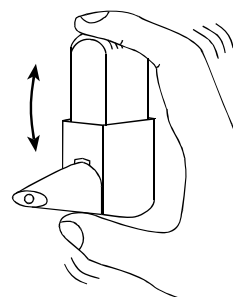


Figure 4a.

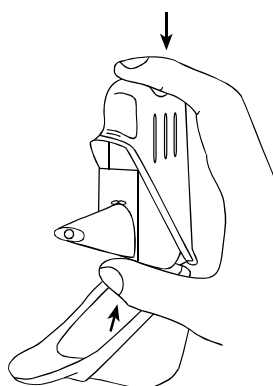
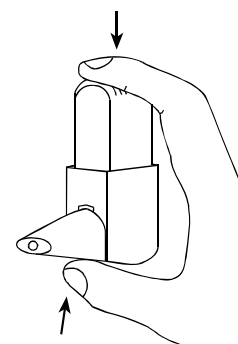


Figure 4b.



C. Inhale

In the sitting or standing position

- Breathe out normally (but NOT into the Easyhaler).
- Place the mouthpiece in your mouth between your teeth and seal your lips tightly around it.
- Take a strong and deep breath through the Easyhaler (Figure 5a or 5b).
- Remove the Easyhaler from your mouth.
- Hold your breath for at least 5 seconds, then breathe normally.

Make sure that you do not breathe out into the Easyhaler, because it could clog up the Easyhaler. If this happens, see section NOTE! (Figures 6a or 6b).

If you have been prescribed more than one dose, repeat points **A**, **B** and **C**.

Put the dust cap back on the mouthpiece.

Close the protective cover, if you are using it.

Rinse

Rinse your mouth and throat and spit out the water.

This reduces the risk of fungal infection (thrush).

NOTE

If you click the Easyhaler by accident, or if you 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.

CLEANING

Clean the mouthpiece at least once a week with a clean dry cloth or tissue. Do not use water or other liquids, the powder is sensitive to moisture. If you use the protective cover, you can take the Easyhaler out of it to wipe it. When 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 Easyhaler has a dose counter which shows how many doses are left (Figure 7a or 7b). The counter turns after every fifth actuation (dose). When the numbers turn 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 even though you can still observe the powder in the clear window on the back of the Easyhaler (Figure 8).

Keep the protective cover for the next Easyhaler.

Figure 5a.

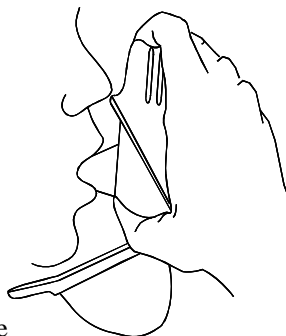


Figure 5b.

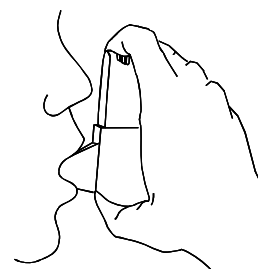


Figure 6a.

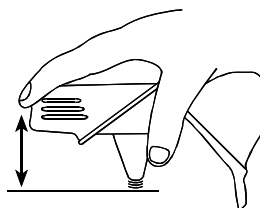


Figure 6b.

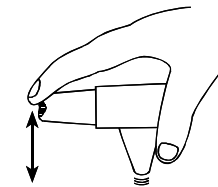


Figure 7a.

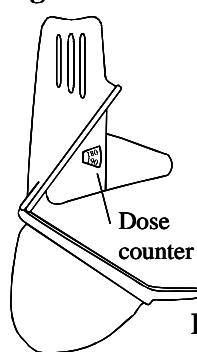


Figure 7b.

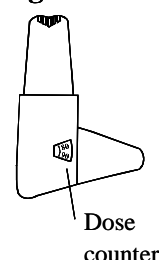


Figure 8.

