

QR code to www.oeh.fi/begb.

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

Package Leaflet: Information for the user

Easyhaler Beclometasone 200 micrograms/dose inhalation powder beclometasone dipropionate

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

1. WHAT EASYHALER BECLOMETASONE IS AND WHAT IT IS USED FOR

Easyhaler Beclometasone is packed in an inhaler called Easyhaler. Beclometasone dipropionate belongs to a group of medicines called corticosteroids (often just called steroids). A very small dose of steroid is needed when it is inhaled. This is because it is inhaled straight to your lungs. Easyhaler Beclometasone works by reducing swelling and irritation in the lungs. They have what is called an 'anti-inflammatory action'.

Easyhaler Beclometasone helps to prevent asthma in people who need regular treatment. This is why they are sometimes called 'preventers'. They need to be used regularly, every day.

Easyhaler Beclometasone will not help treat sudden asthma attacks where you feel breathless.

- A different medicine is used for treating sudden attacks (called a 'reliever').
- If you have more than one medicine, be careful not to confuse them.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE EASYHALER BECLOMETASONE

Do not use Easyhaler Beclometasone if you are allergic (hypersensitive) to:

- beclometasone dipropionate
- lactose (which contains small amount of milk proteins)
- any of the other ingredients of Easyhaler Beclometasone (listed in Section 6).

Do not use Easyhaler Beclometasone if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before using Easyhaler® Beclometasone.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before using Easyhaler Beclometasone:

- if you have ever been treated for tuberculosis (TB)
- if you are using Easyhaler Beclometasone at the same time as taking steroid tablets. Also if you have just finished taking steroid tablets. In both cases, you should carry a steroid warning card until your doctor tells you not to carry one.

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

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

Children

Easyhaler Beclometasone is not recommended for use in children

Other medicines and Easyhaler Beclometasone

- Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines, including herbal medicines and medicines obtained without a prescription. Remember to take this medicine with you if you have to go into hospital.
- Some medicines may increase the effects of Easyhaler Beclometasone and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Easyhaler Beclometasone with food and drink

You can use Easyhaler Beclometasone at any time of day, with or without food.

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.

Driving and using machines

Easyhaler Beclometasone is not likely to affect you being able to drive or use any tools or machines.

Easyhaler Beclometasone contains lactose

Lactose contains small amounts of milk proteins, which may cause allergic reaction. If you have been told by your doctor that you do not tolerate certain kinds of sugars, talk to your doctor before using this medicine. The amount of lactose in Easyhaler Beclometasone (approximately 7mg per dose) does not normally cause problems in lactose intolerant people.

3. HOW TO USE EASYHALER BECLOMETASONE

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

Using this medicine

- **It takes a few days for this medicine to work and it is very important that you use it regularly.**

The usual dose for Easyhaler Beclometasone is:

Adults (over 18 years) including the Older people:

Your doctor will start you on a dose appropriate to your condition.

For prevention and long-term use the usual starting dose is one puff (actuation) (200 micrograms) twice a day. This may be increased to three to four puffs (actuactions) (600-800 micrograms) per day, and then reduced when your condition has improved. The total daily dose may be given in two, three or four divided doses.

Children:

Easyhaler Beclometasone is not recommended for use in children.

If you are using high doses of an inhaled steroid for a long time you may sometimes need extra steroids for example during stressful circumstances such as a road traffic accident or before an operation. Your doctor may decide to give you extra steroid medicines during this time.

If you use more Easyhaler Beclometasone than you should

If you use more than you should, **talk to your doctor as soon as possible.**

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 Beclometasone

- Take the next dose when it is due.
- Do not take a double dose to make up for a forgotten dose.

If you stop using Easyhaler Beclometasone

- **Do not stop treatment** even if you feel better unless told to do so by your doctor.

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

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 cause side effects, although not everybody gets them.

If you notice any of the following serious side effects, stop using this medicine and talk to your doctor straight away. You may need urgent medical treatment.

- allergic reactions (affects less than 1 in 100 people) – the signs include skin rashes, redness, itching or weals like nettle rash or hives
- severe allergic reactions (affects less than 1 in 10,000 people) - the signs include swelling of your face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed and collapse
- your breathing or wheezing gets worse straight after using your inhaler.

Talk to your doctor as soon as possible if:

- after 7 days of using Easyhaler Beclometasone your shortness of breath or wheezing does not get better, or gets worse.

Other side effects include:

Very Common (may affect more than 1 in 10 people):

- thrush in the mouth and throat

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

- sore tongue or throat
- hoarseness of voice
- cough

Problems with your mouth and throat can be reduced by doing certain things straight after inhaling your dose. These are brushing your teeth, rinsing your mouth or gargling with water and spitting it out. Tell your doctor if you have these problems with your mouth or throat, but do not stop treatment unless you are told to.

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

- a round, puffy face (called 'moon face')
- weight gain, especially on the neck and shoulders
- shortness of breath

Using high-dose inhaled corticosteroids over a long time can cause, in very rare cases, systemic effects. These include:

- decrease in bone mineral density (thinning bones)

- growth retardation (slowing of growth) in children and adolescents. Your doctor may wish to check the height of your children regularly
- increase pressure in your eyes (glaucoma)
- cataract
- lower respiratory tract infection
- problems with how your adrenal glands work (adrenosuppression) - causing loss of appetite, abdominal pain, weight loss, tiredness, feeling sick, being sick, feeling faint, sweating and possible fits, you should consult your doctor. This is particularly important if you have been exposed to stress such as surgery, infection, an acute attack of asthma, or other serious illness. Your doctor may carry out blood test from time to time to monitor the level of steroids in your body.

Your doctor will help stop this happening by making sure you use the lowest dose of steroid which controls your symptoms.

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

Although the frequency is not known, the following side effects may also occur:

- Sleeping problems, depression or feeling worried, restless, nervous over-excited or irritable. These effects are more likely to occur in children.
- Blurred vision

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 effect directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE EASYHALER BECLOMETASONE

- Keep this medicine out of the sight and reach of children.
- Before the first use: store in unopened foil bag.
- After opening the foil bag: store below 25 °C protected from moisture. It is recommended to keep the Easyhaler in its protective cover.
- If your Easyhaler Beclometasone gets damp, you need to replace it with a new one.
- Replace Easyhaler Beclometasone with a new one at the latest 6 months after you opened the foil bag, write down the date you opened the bag to help you remember.
- Do not use Easyhaler Beclometasone after the expiry date which is stated on the Easyhaler Beclometasone label and carton (EXP). The expiry date refers to the last day of that month.
- 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.
- If you are told to stop using this medicine return any unused Easyhaler Beclometasone to your pharmacist to be destroyed.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Easyhaler Beclometasone contains

- The active substance is Belometasone dipropionate
- The other ingredient is lactose monohydrate (which contains small amounts of milk proteins).

What Easyhaler Beclometasone looks like and contents of the pack

The Easyhaler Beclometasone comes in a laminate pouch to keep the powder dry. Please see the section below which identifies each part of your Easyhaler.

Marketing Authorisation Holder and Manufacturer

Orion Corporation, Orionintie 1, FIN-02200, Espoo, Finland

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

Orion Pharma (UK) Limited, Abbey Gardens, 4 Abbey Street, Reading, RG1 3BA, United Kingdom

This leaflet was last revised in March 2021

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/begb.

QR code to www.oeh.fi/begb.

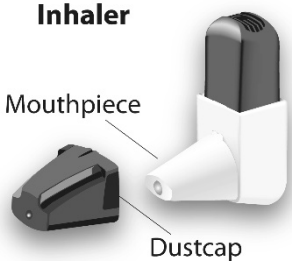
How to use the Easyhaler inhaler

About your Easyhaler

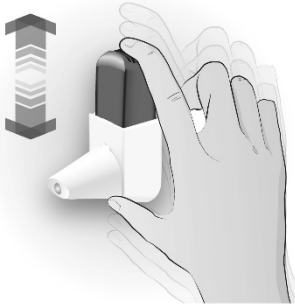
Easyhaler Beclometasone may be different to inhalers you have used in the past. Therefore it is very important that you use it properly as using incorrectly can lead to you not receiving the right amount of medicine. This could make you very unwell or could lead to your asthma not being treated as it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

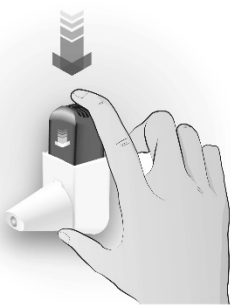
Your doctor, nurse or pharmacist will show you how to use your inhaler properly. Make sure you understand the correct way to use the inhaler. If you are unsure contact your doctor, nurse or pharmacist. As with all inhalers, caregivers should ensure that children prescribed Easyhaler Beclometasone use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


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 6 months of removing from the foil bag.</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, hold breath for at least 5 seconds, 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.

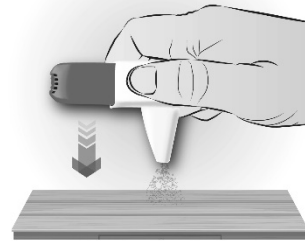
After you have used the inhaler:

- 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 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.

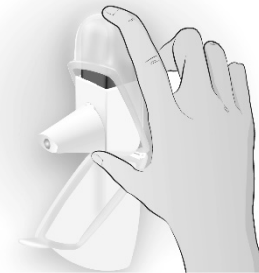
Using the Easyhaler with a protective cover

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.

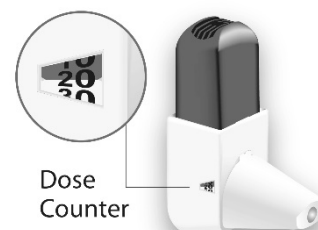


When to switch to a new Easyhaler

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.