

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.

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

- Instructions on how to use this Easyhaler[®] are given as a step-by step guide below
- **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 (actuations) (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.

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.

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. 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 laminate pouch. After opening the laminate pouch: 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 laminate pouch, write down the date you opened the pouch 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

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INSTRUCTIONS FOR USING YOUR EASYHALER

Easyhaler Beclometasone 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 (Figures 1 and 2)

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 Beclometasone”.

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® BECLOMETASONE

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 (Figure 3a or 3b)

Shake the Easyhaler vigorously up and down 3–5 times, to allow proper powder flow and a correct dose. After shaking, hold the Easyhaler in the **upright** position.

B. Click (Figure 4a or 4b)

Press the Easyhaler **once** between your finger and thumb until you hear a click 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!” see below (Figure 6a or 6b).

Figure 1.

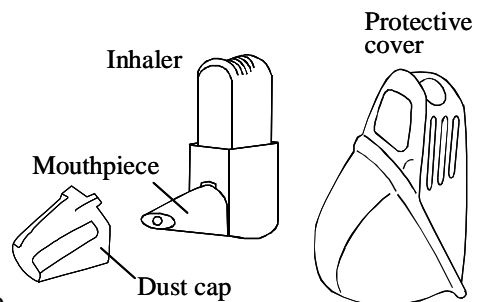


Figure 2.

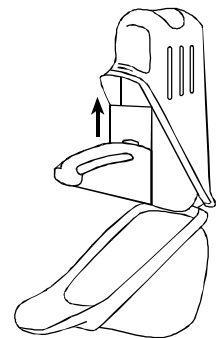


Figure 3a.

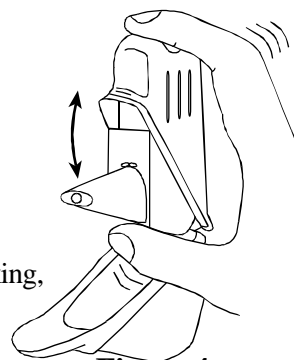


Figure 3b.

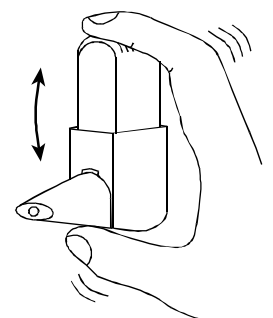


Figure 4a.

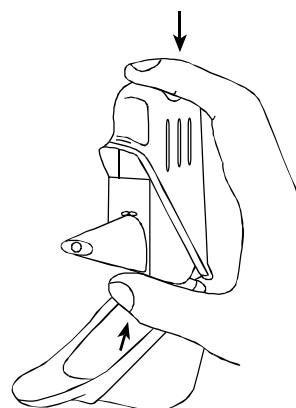
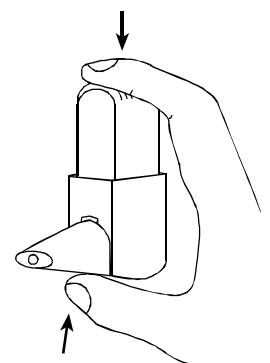


Figure 4b.



C. Inhale (Figure 5a or 5b)

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.

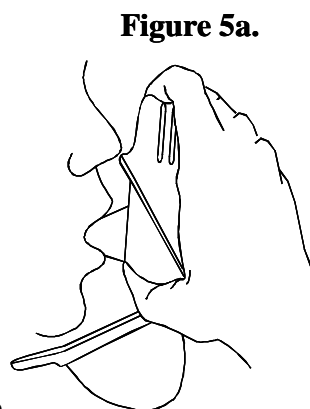


Figure 5a.



Figure 5b.

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

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.

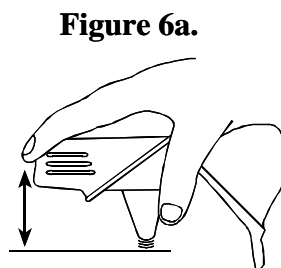


Figure 6a.

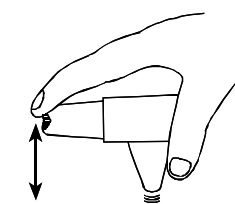


Figure 6b.

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 (Figures 7a, 7b and 8)

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.

Replace your Easyhaler beclometasone with a new one no later than 6 months after you opened the laminate pouch.

Figure 7a.

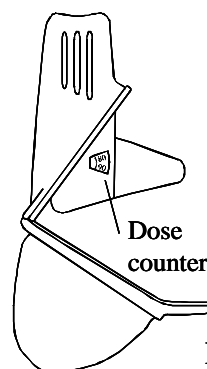


Figure 7b.

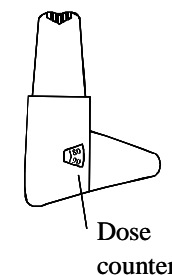


Figure 8.



Write down the date you opened the pouch to help you remember.