

BECLOMET EASYHALER INHALATION POWDER

Beclometasone dipropionate 200mcg/dose

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Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What Beclomet Easyhaler is used for

Beclomet Easyhaler is a medicine called “**preventer**”. It treats the inflammation and it is used to prevent symptoms of asthma. It belongs to a group of medicine called corticosteroids.

Beclomethasone will NOT stop an asthma attack that has already started. Therefore you always need to have a fast acting bronchodilating (medications used to help improve airflow into the lungs) “**reliever**” (a beta₂-agonist) with you.

Beclometasone powder is packed in an inhaler called Easyhaler. You inhale the powder into your lungs through the mouthpiece of the inhaler.

How Beclomet Easyhaler works

Beclomet Easyhaler works by reducing swelling and inflammation in the lungs.

Before you use Beclomet Easyhaler

- When you must not use it

Do not use Beclomet Easyhaler, - if you are allergic (hypersensitive) to beclometasone or lactose monohydrate (which contains small amounts of milk proteins).

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

- Before you start to use it

Pregnancy and breast-feeding

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

Talk to your doctor **before** you use Beclomet Easyhaler, if you have:

- pulmonary tuberculosis (a bacterial infection that involves the lungs)

Important information about some of the ingredients of Beclomet Easyhaler

Beclomet Easyhaler inhalation powder contains such a small amount of lactose (7mg/dose), 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.

- Taking other medicines

Tell your doctor, if you are using:

- nasal medicines containing corticosteroids
- corticosteroid tablets

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

How to use Beclomet Easyhaler

- How much to use

Your doctor has prescribed a suitable strength and dose for you. Follow your doctor's instructions carefully. Usually you take 1-2 doses of this medicine 2-4 times a day.

The usual maintenance dose:

Adults: One to two inhalations (200-400 mcg) twice daily. If needed, the dose can be increased up to 1600 mcg/day divided in two to four doses and subsequently reduced when asthma has stabilized.

6 – 12 years old children: One inhalation (200mcg) two times daily. In more severe cases, the dose can be increased up to 800 mcg/day divided in two to four doses and subsequently reduced when asthma has stabilized.

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).

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

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

- If you forget to use it

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 the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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.

While you are using it**- Things you must do**

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

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.

Replacing corticosteroid tablets with Beclomet Easyhaler:

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 few weeks. If you feel unwell during this transfer period, contact your doctor, but do not stop using Beclomet Easyhaler.

- Things you must not do

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

- Things to be careful of

Orally inhaled corticosteroids may cause a reduction in growth velocity in pediatric patients. The growth of children receiving orally inhaled corticosteroids should be monitored routinely.

In addition to the preventer, Beclomet Easyhaler, you also need a bronchodilating reliever: Beclometasone 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 Beclomet Easyhaler (preventer).

Driving and using machines

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

Side effects

Like all medicines, Beclomet Easyhaler can also cause side effects, although not everybody gets them.

Common side effects

- oral, pharyngeal or laryngeal candidiasis (thrush in the mouth and throat);
- hoarseness;
- cough;
- sore throat and irritation of throat

Rare side effects

- eosinophilic pneumonia (lung diseases in which eosinophils [a type of white blood cell] appear in increased numbers in the lungs and bloodstream) ;
- allergic reactions, including urticaria (hives), angioedema (swelling that is similar to hives, but the swelling is under the skin instead of on the surface) and rash;
- bronchospasm (tightening of the muscles around the bronchial tubes)
- growth suppression (inhibition of growth)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

Reaction Monitoring by visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and disposal of Beclomet Easyhaler**- Storage**

Keep out of the reach and sight 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.

Replace Beclomet Easyhaler 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 Beclomet Easyhaler gets damp, you need to replace it with a new one.

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

- Disposal

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.

Product Description**- What it looks like**

White or almost white powder.

- Ingredients

- Active ingredient
The active substance is beclometasone dipropionate

- Inactive ingredient
The other ingredient is lactose monohydrate (which contains small amounts of milk proteins)

- MAL number
MAL19970047AZ

Manufacturer

Orion Corporation
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02200 Espoo, Finland

Product Registration Holder

ORION PHARMA (MY) SDN. BHD.
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