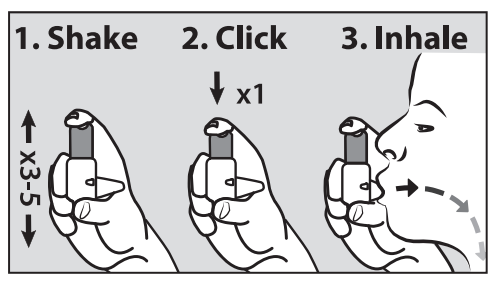


BECLOMET EASYHALER® 200 MCG/ DOSE INHALATION POWDER

Product Description
BECLOMET EASYHALER is an inhalation powder packed into a multiple dose powder inhaler from which the patient can accurately deliver the individual drug doses. It is for oral inhalation. The product contains 200 mcg of beclomethasone dipropionate per metered dose. The dose, which the patient gets through the mouthpiece of the device is 180 mcg.
BECLOMET EASYHALER contains 200 doses of finely powdered beclomethasone dipropionate mixed in a small quantity of lactose. The amount of drug received by the patient (180 mcg/dose) corresponds to that from two puffs of the freon-based beclomethasone inhalation aerosol with a metered dose of 100 mcg/ dose. The dose to be inhaled is released from the container by pressing the device between the thumb and the forefinger. This is followed by inhalation through the device. As a result, beclomethasone dipropionate particles are transferred to their target, the lungs. Use of the BECLOMET EASYHALER does not require coordination of actuation of the dose and inhalation.

Pharmacodynamics
Pharmacotherapeutic group: Glucocorticoids. ATC code: R03BA01.
Beclomethasone dipropionate is a synthetic steroid derivative. It has a potent local anti-inflammatory
effect on the respiratory mucosa when administered topically. Long-term studies have shown that after the initiation of inhaled beclomethasone dipropionate in patients with bronchial asthma, the dose of systemic corticosteroids may be gradually reduced. There is no evidence that
the drug damages the tracheobronchial mucosa or increases the incidence of respiratory infections.
The exact mechanisms responsible for the anti-inflammatory effect of beclomethasone dipropionate are unknown..

Pharmacokinetics
Approximately 10-25 % of the inhaled active substance reaches the lungs and the biggest fraction of the dose is retained in the upper airways and mouth and is swallowed. The active substance absorbed from the lungs is ultimately metabolized in the liver. Beclometasone dipropionate is metabolized to active 17-beclometasone mono-propionate, and free beclometasone and metabolites are mainly excreted to faeces. Less than 10 % of the active substance and its metabolites is excreted in urine.

Indications
Treatment of bronchial asthma

Contraindications
Hypersensitivity to beclomethasone dipropionate or lactose monohydrate (which contains small amounts of milk proteins).

Side Effects
The most common adverse effects include candidiasis of the mouth and throat, hoarseness, cough,
throat irritation and sore throat.
Other adverse effects include bronchospasm, eosinophilic pneumonia, allergic reactions
(including anaphylactic shock, urticaria, rash, angioedema), easy bruising and skin thinning
Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for
prolonged periods. These may include Cushing's syndrome, Cushingoid features, adrenal suppression,
growth retardation in children and adolescents, decrease in bone mineral density, cataract, glaucoma
and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity,
sleep disorders, anxiety, depression or aggression (particularly in children).

Vision, blurred has been reported in uncommon frequency.

Special Precautions/Warnings
Patients should be taught the proper use of EASYHALER inhaler to ensure that the active substance reaches the target areas in the lungs. They should be aware that BECLOMET EASYHALER inhalation powder has to be used regularly for optimum benefit and should not be stopped abruptly.

BECLOMET EASYHALER is not intended for the treatment of acute asthma attack. The therapeutic effect of beclomethasone occurs only after a few days' treatment and reaches its maximum after several weeks.

To reduce the risk of Candida infection patients should be advised to rinse their mouths properly after each drug administration and spit out the water. Oral candidiasis appears to be rapidly controlled by local antimycotic therapy, without the need to discontinue treatment with BECLOMET EASYHALER.

Special care is needed in patients with viral, bacterial and fungal infections of the eye or of the mouth or respiratory tract. In case of bacterial infection of the respiratory tract an adequate antibiotic co-medication may be required.
Special care and adequate specific therapeutic control of patients with pulmonary tuberculosis is necessary before starting therapy with beclometasone dipropionate.
Rarely inhalation therapy may cause bronchospasm after dosing. In this event, treatment with BECLOMET EASYHALER must be immediately discontinued and, if need be, replaced with another therapy

The transfer of patients treated with oral steroids to the inhaled steroid and their subsequent management needs special care. The patient should be in a reasonably stable state before giving inhaled steroid in addition to this usual maintenance dose of systemic steroid. After about a week, gradual withdrawal of the systemic steroid is started by reducing the daily dose gradually. Transferred patients whose adrenocortical function is impaired should carry a warning card indicating that they need supplementary systemic steroid during periods of stress e.g. surgery, infection or worsening asthma attacks.

Should acute symptoms of asthma occur, a short acting beta$_2$-agonist bronchodilator should be used to relieve them. Increasing use of bronchodilators, in particular short-acting inhaled beta$_2$-agonists to relieve symptoms indicates deterioration of asthma control. If patients find that short acting relief bronchodilator treatment becomes less effective or they need more inhalations than usual, medical attention must be sought. In this situation patients should be reassessed and consideration given to the need for increased anti-inflammatory therapy (e.g. higher doses of inhaled corticosteroids or a course of oral corticosteroids). Severe exacerbations of asthma must be treated in the normal way.

Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). It is important, therefore, that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control of asthma is maintained.
Prolonged treatments with high doses of inhaled corticosteroids, particularly higher than the recommended dose, may result in clinically significant adrenal suppression. Additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.

It is recommended that the height of children receiving prolonged treatment with inhaled
corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim
of reducing the dose of inhaled corticosteroid, if possible, to the lowest dose at which effective control
of asthma is maintained. In addition, consideration should be given to referring the patient to a
paediatric respiratory specialist.

Visual disturbance
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents
with symptoms such as blurred vision or other visual disturbances, the patient should be considered
for referral to an ophthalmologist for evaluation of possible causes which may include cataract,
glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported
after use of systemic and topical corticosteroids.

Transferring from oral to inhaled corticosteroids can exacerbate allergies.
Some patients feel unwell for approximately 2 weeks during the withdrawal of treatment with systemic corticosteroids, even though their respiratory function remains the same or even improves. Such patients should be encouraged to continue treatment with BECLOMET EASYHALER.
In case of massive mucous secretion in the respiratory tract, desobstruction and short-term therapy with high doses of a systemic corticosteroid can be necessary to ensure efficacy of inhaled beclometasone.

Effects on ability to drive and use machines
No effects on ability to drive and use machines have been observed.

Drug Interactions
If used concomitantly with systemic or intranasal steroids the suppressive effect on adrenal function will be additive. Beclomethasone is less dependent on CYP3A metabolism than some other corticosteroids, and in general interactions are unlikely; however the possibility of systemic effects with concomitant use of strong CYP3A inhibitors (e.g. ritonavir, cobicistat) cannot be excluded, and therefore caution and appropriate monitoring is advised with the use of such agents.

Use in Pregnancy and Lactation
Pregnancy
The safety of Beclomethasone dipropionate for use in human pregnancy has not been established. Reproduction toxicity studies in animals have revealed an increased incidence of foetal damage, the significance of which is considered uncertain in man. Since the possibility of intrauterine growth retardation and adrenal suppression in the new-born baby must be considered, the needs of the mother must be carefully weighed against the risk to the foetus.
Breast-feeding
It is reasonable to assume that the active substance is distributed into the breast milk, but at the dosages used for direct inhalation, there is low potential for significant levels in breast milk.

Dosage and Administration
The preparation is intended for oral inhalation only. This preparation is particularly useful for patients who are unable to use metered dose inhaler properly and for patients to whom the use of inhalation aerosol causes irritation of airways. For optimum results, BECLOMET EASYHALER inhalation powder should be used regularly.

Patients who have received systemic corticosteroids should continue them for a week after having started to use BECLOMET EASYHALER inhalation powder. Thereafter, the systemic treatment can be reduced gradually under careful monitoring.

Adults: The usual maintenance dose is 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.

Children 6 - 12 years: One inhalation (200 mcg) two times daily according to the clinical response. 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.

Instructions for Use/ handling:
Patients have to be instructed to perform a strong and deep inhalation through the Easyhaler device. Patients have to be instructed not to exhale into the device. Illustrated user's instructions for use accompany each package.

Overdosage and Treatment
The acute toxicity of beclomethasone dipropionate is low. Also if high doses were used inadvertently, no special emergency action needs to be taken. Treatment should be continued at the recommended dose to control asthma.

Packaging
A User Package containing 1 unit of BECLOMET EASYHALER 200 mcg/ dose inhalation powder in the inhaler device, and instruction for use.
Storage : Do not store above 30 °C.
Keep out of reach of children.
Shelf life : 3 years when stored in laminate pouch; 6 months after opening of the pouch. Beclomet Easyhaler inhalation powder should not be used after these dates.

Manufactured by
Orion Corporation
Espoo, Finland

Product Registration Holder:
Orion Pharma (MY) Sdn. Bhd
E-20-01, Menara SUEZCAP 2,
KL Gateway, No. 2, Jalan Kerinchi,
Gerbang Kerinchi Lestari
59200, Kuala Lumpur, Malaysia

MAL19970047AZ

159739-1

4-8-2022/PS

ORION PHARMA
Proof Colors:
Black
Size : 200 x 620 mm
Minimum Font 9 pt
Omnes Regular & Bold
Pharmacode No. 170

INSTRUCTIONS FOR USE BECLOMET EASYHALER®

Beclomethasone dipropionate inhalation powder

Read the following instructions before using BECLOMET EASYHALER inhalation powder. Follow the instructions carefully.

With BECLOMET EASYHALER multidose powder inhaler you can inhale beclomethasone dipropionate to your lungs without needing to inhale any propellants.

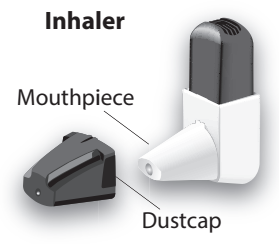
The powder inhaler contains 200 doses of beclomethasone dipropionate an anti-inflammatory drug substance, which with regular use, effectively treats asthma. The therapeutic effect occurs after a few days of treatment. Please note that BECLOMET EASYHALER is not intended for the treatment of acute asthma attacks!

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.

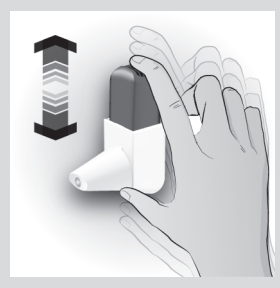


HOW TO USE CORRECTLY

Step 1: SHAKE

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

SHAKE x 3-5



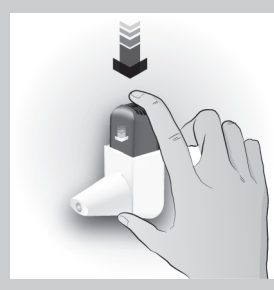
Important points to remember

- 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**

CLICK x 1



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.

INHALE

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:

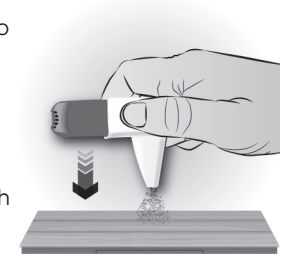
- Put the dust cap back on the mouthpiece. It stops the inhaler going off by accident.
- After you have taken the dose, rinse your mouth with water, and spit it out and/or brush your teeth.

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:

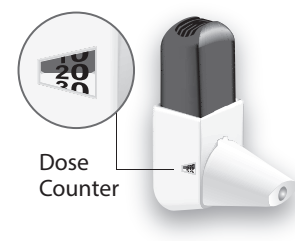
- Keep the inhaler in the upright position when clicking it
- Replace the dustcap after taking the dose as this stops the inhaler going off by accident.

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.

Revision Date: June 2022