

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.

Properties

Beclomet Easyhaler™ inhalation powder contains beclomethasone dipropionate, which is a synthetic steroid derivative. The clinical efficacy of beclomethasone dipropionate in the treatment of asthma is based on its strong topical anti-inflammatory activity on the mucosa of the lungs. Inhaled beclomethasone dipropionate has not been found to have the systemic effects typical of steroids at daily doses below 1500 mcg. 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 constantly reduced. There is no evidence that the drug would damage tracheobronchial mucosa or increase the incidence of respiratory infections. Approximately 10-25 % of the inhaled drug dose reaches the lungs and the biggest fraction of the dose is retained in the upper airways and mouth and is swallowed.

Beclomet Easyhaler™ treatment should be regular because the beneficial effects of the medication will appear only after a few days' use, and the maximal effect will be attained only after several weeks. Beclomethasone dipropionate has no effect in an acute attack.

When shifting from freon-based metered dose aerosols to inhalation powders, it is optimal to choose a dispenser, which is used in the same way as the patient's previous inhaler except for the hand-lung coordination. Also similarity of the drug doses between the new and previous dispenser is an advantage to the patient.

The clinical efficacy and tolerability of Beclomet Easyhaler™ are the same as those of a corresponding dose of beclomethasone dipropionate from a freon-based inhalation aerosol given through an inhalation chamber.

Indications

Treatment of bronchial asthma

Contraindications

Hypersensitivity to the components of Beclomet Easyhaler™ inhalation powder. Special care is necessary in patients with pulmonary tuberculosis.

Side Effects

Normally used inhaled doses of beclomethasone dipropionate are well tolerated. Suppression of hypothalamic-pituitary-adrenal (HPA) function has been reported in adults who received over 1500 mcg daily doses of inhaled beclomethasone dipropionate.

Oral, pharyngeal or laryngeal candidiasis occurs in some patients.

These infections can be treated with antifungal therapy while continuing with inhaled beclomethasone dipropionate.

Hoarseness, cough, sore throat and irritation of throat have also been reported.

Rare cases of eosinophilic pneumonia or allergic reactions, including urticaria, angioedema, rash and bronchospasm have been reported.

Vision, blurred has been reported in unknown frequency.

Cases of growth suppression have been reported for orally inhaled corticosteroids (See Pediatric Use).

Special Precautions/Warnings

Patients should be taught the proper use of Easyhaler inhaler to ensure that the drug reaches the target areas in the lungs. They should be aware that Beclomet Easyhaler™ inhalation powder has to be used regularly for optimum benefit.

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 after that.

In the majority of patients no significant adrenal suppression occurs until doses of 1500 mcg per day are exceeded. Reduction of plasma cortisol levels has been reported in some patients who received 2000 mcg per day of inhaled beclomethasone dipropionate.

Patients should be instructed to contact their physician immediately when episodes of asthma that are not responsive to bronchodilators occur during the treatment with Beclomet Easyhaler™ inhalation powder. During such episodes patients may require therapy with systemic corticosteroids.

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.

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

Effects on ability to drive and use machines

Beclomet Easyhaler™ Inhalation powder is unlikely to affect ability to drive or operate machinery.

Drug Interactions

The use of inhaled sympathomimetic drug prior to inhalation of steroid may improve the lung distribution of the latter. If used concomitantly with systemic or intranasal steroids the suppressive effect on adrenal function may be potentiated.

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.

Pediatric Use

Controlled clinical studies have shown that orally inhaled corticosteroids may cause a reduction in growth velocity in pediatric patients. This effect has been observed in the absence of laboratory evidence of hypothalamic-pituitary-adrenal (HPA) axis suppression, suggesting that growth velocity is a more sensitive indicator of systemic corticosteroid exposure than some commonly used tests of HPA axis function. The long term effects of this reduction in growth velocity associated with orally inhaled corticosteroids, including the impact on final adult height, are unknown. The potential for "catch up" growth following discontinuation of treatment with orally inhaled corticosteroids has not been adequately studied. The growth of pediatric patients receiving orally inhaled corticosteroids should be monitored routinely (e.g. via stadiometry). The potential growth effects of prolonged treatment should be weighed against clinical benefits obtained and the availability of safe and effective non-corticosteroid treatment alternatives. To minimize the systemic effects of orally inhaled corticosteroids, each patient should be titrated to his/her lowest effective dose.

Use in Pregnancy and Lactation

The use of beclomethasone dipropionate in pregnancy requires that the possible benefits of the drug be weighed against the possible hazards.

In animals, the usage of steroid in pregnancy have been proved to be teratogenic and it is reasonable to assume that the drug is excreted in milk. Thus, it should be used in pregnant women and nursing mothers only when necessary.

Since adrenal insufficiency may occur in neonates born to women who have received corticosteroids during pregnancy, these neonates should be monitored carefully.

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. In high doses, however, suppression of HPA function may occur. No special emergency actions need to be taken. Treatment should be continued at the recommended dose to control asthma. HPA axis recovers in a couple of days.

If inhaled steroid is used excessively over a long period this could lead to adrenal suppression. In such a case patient should be transferred to oral corticosteroid therapy, and when the condition has stabilized, be returned to inhaled therapy at the recommended dose.

Packing

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 25 °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

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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 attack!

A. PREPARING THE POWDER INHALER FOR FIRST USE

1. Remove the powder inhaler from the laminate pouch.

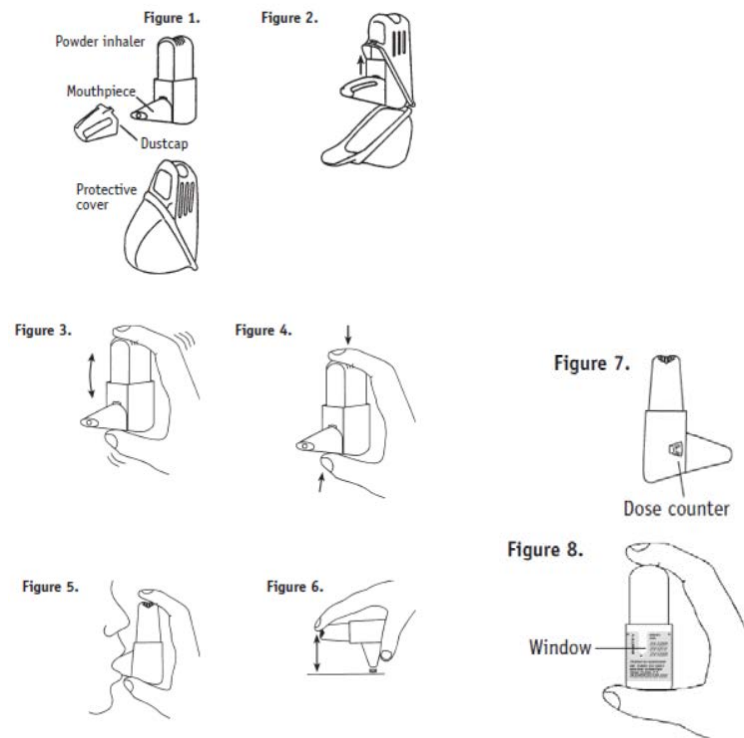
If you do not use the protective cover move on to point B.

If you use the protective cover:

2. Open the protective cover.

3. Insert the powder inhaler into the protective cover (Figure 2). The dustcap on the mouthpiece (Figure 1) prevents accidental actuation of the inhaler when inserting it into the protective cover.

4. If you are not using the device immediately, close the protective cover. Store the inhaler in the protective cover when not in use.



B. DELIVERING THE MEDICATION

1. Remove the dustcap (Figure 1).

2. **Shake the device prior to each dose** (Figure 3).

After shaking, hold the device in the upright position.

3. **Release the dose.**

Press the device only once between your thumb and forefinger until you hear a click (Figure 4).

Let the device return to the original position. Keep holding the device in the upright position.

Note! If you think that you have released more than one dose, remove the doses from the mouthpiece by tapping it against the palm of your hand or, for example, a table, as shown in Figure 6. After this, repeat from point 2 (Shake the device...).

4. **Inhale the drug dose** according to the following instructions:

- First breath out normally.
- Then place the mouthpiece in your mouth between your teeth and close your lips tightly around the mouthpiece.
- **Take a strong and deep breath through your mouth (Figure 5).**
- Remove the inhaler from your mouth and hold your breath for 5 to 10 seconds.
- When you feel a sweet taste in your mouth, which is not felt by everybody, you can be sure that you have received the dose.

If you have been prescribed more than one dose, repeat points 2, 3 and 4 (Shake the device..., Release the dose, Inhale the drug...).

5. **Put the dustcap back on the mouthpiece.**

6. Rinse your mouth thoroughly. Do not swallow the water, spit it out.

CLEANING

The mouthpiece can be cleaned with a dry cloth. **Never use water!**

STORAGE

Do not store above 25°C.

WHEN SHOULD THE DEVICE BE RENEWED?

The expiry date is printed on the package. Do not use the product if it is expired. Once the inhaler is removed from its laminate pouch, it must be used within six months.

Do not use the product if it has been outside the pouch longer than six months.

The inhaler has a dose counter which indicates the number of remaining doses (Figure 7). The counter turns after every five actuations. When the counter turns red there are 20 doses left.

A clear window on the back of the inhaler allows viewing of the powder (Figure 8). The device must be replaced when the dose counter indicates zero.

IMPORTANT

Release the dose from the device only when you are going to inhale the medication. If you have accidentally released the dose, remove it from the mouthpiece by tapping it against the palm of your hand or, for example, a table (Figure 6).

Inhalation powder should not be exposed to humidity. If the powder becomes damp, it is not suitable for use and should be disposed of.

Never exhale into the powder inhaler, because the humidity of exhalation damages the product.

Rinse your mouth thoroughly after each drug administration. Do not swallow the water, spit it out.