



Beclomin[®] 100 Inhaler

Beclomethasone Dipropionate
Steroidal inhalant

COMPOSITION

Beclomin[®] 100 Inhaler : Metered-dose aerosol delivers Beclomethasone Dipropionate BP 100 µg per puff.

PHARMACOLOGY

Beclomethasone Dipropionate (BDP) has both local anti-inflammatory and immunosuppressive activity. The mechanisms behind these actions involve a number of factors. Firstly, the drug inhibits the adherence of neutrophils and monocyte-macrophages to the capillary endothelial cells of the inflamed area. Secondly, beclomethasone blocks the effect of macrophage migration inhibitory factor. Beclomethasone also decreases the activation of plasminogen to plasmin and by inhibition of phospholipase A₂ activity, it reduces the formation of prostaglandin and leukotrienes in the local tissue. BDP inhibits the late-response to allergen. Inhaled BDP is very useful in minimizing the oral dose of the steroid required to control asthma.

After inhalation, about 25% of the dose reaches the lungs and is available for absorption from this site. The remainder is deposited on the delivery device or swallowed. There is rapid metabolic inactivation of most of the swallowed portion of BDP to BMP (Beclomethasone Monopropionate) during its first passage through the liver. The lung tissue rapidly hydrolyzes BDP to BMP which in turn is hydrolysed more slowly to beclomethasone. The liver also metabolises BDP to BMP and further converts it to polar metabolites. Excretion is mainly in the feces (35-76% of the dose in 96 hours) and primarily as polar metabolites. Up to 14% of the dose is excreted as polar metabolites in urine. BDP is bound to plasma proteins to the extent of about 87%.

INDICATION

Beclomin[®] 100 given by inhalation offers preventive treatment for asthma. It provides effective anti-inflammatory action in the lungs without the problems of systemic corticosteroid treatment.

Beclomin[®] 100 inhaler is indicated in the prophylactic management of mild, moderate, and/or severe asthma in adults or children.

Mild asthma: Patients requiring symptomatic bronchodilator medication on a regular basis.

Moderate asthma: Patients with unstable or worsening asthma despite prophylactic therapy or bronchodilator therapy alone.

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Severe asthma: Patients with severe chronic asthma and those who are dependent on systemic corticosteroids for adequate control of symptoms.

DOSAGE AND ADMINISTRATION

Adults: The usual starting dose is 200 µg twice daily. In more severe cases, dosage may be started at or increased to 600 to 800 µg per day and subsequently reduced when adequate control has been established. The total daily dose may be administered as two, three or four divided doses.

Children: 50 to 100 µg two, three or four times daily, according to the response. Alternatively, 100 µg or 200 µg daily may be administered. The usual starting dose is 100 µg twice a day.

Treatment with inhaled Beclomethasone should be continued at a minimum dose sufficient to control asthma.

There is no need to adjust the dose in elderly patients or in those with hepatic or renal impairment.

CONTRAINDICATION AND PRECAUTION

Beclomethasone is contraindicated in patients with known sensitivity to it or any of its ingredients.

Special care is necessary in patients with active or quiescent pulmonary tuberculosis. Beclomethasone inhaler should not be used regularly and should not be stopped abruptly.

SIDE EFFECT

Candidiasis of the mouth and throat (thrush) occurs in some patients, the incidence increases with dose greater than 400 µg per day and with previous infection. Patients may find it helpful to rinse their mouth thoroughly with water after using the inhaler. In some patients it may cause hoarseness or throat irritation. As with other inhalation therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This responds to fast-acting bronchodilator. The preparation should be discontinued immediately.

OVERDOSE

Acute: Inhalation of the drug in doses in excess of those recommended may lead to temporary suppression of adrenal function. This does not necessitate emergency action to be taken.

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Chronic: Use of inhalation in excess of 1500 µg per day over prolonged periods may lead to some degree of adrenal suppression.

DRUG INTERACTION

Beclomethasone inhaler has no known drug interactions.

USE IN PREGNANCY AND LACTATION

Cumulative experiment with Beclomethasone inhaler suggests that it has no adverse effects on fetal development.

The amount of Beclomethasone (given by inhalation) absorbed by a breast-fed infant can be assumed to be negligible.

STORAGE CONDITION

The inhaler should be stored below 30°C protected from direct sunlight & heat. The canister should not be broken, punctured or burnt, even when apparently empty. Keep away from eyes. Rinse mouth thoroughly after each dose. Keep out of reach of children.

HOW SUPPLIED

Beclomin[®] 100 Inhaler; 200 puffs : Each inhaler delivers minimum 200 puffs (100 µg/puff).

