

BECLOMIN 250 HFA INHALER
1.6.3 Patient information leaflet (PIL)

29 April 2019

Beclomin

Beclometasone Dipropionate BP 50 or 100 or 250 mg / puff

HFA Inhaler
200 puffs

COMPOSITION

Each single actuation provides: 50 or 100 or 200 micrograms of Beclometasone dipropionate from the actuator.

INDICATION

Beclometasone 50, 100 & 250 HFA Inhaler is indicated in the prophylactic management of mild, moderate or severe asthma in adults or children.

Beclometasone dipropionate given by inhalation offers preventative treatment for asthma. It provides effective anti-inflammatory action in the lungs with a lower incidence and severity of adverse effects than those observed when corticosteroids are administered systemically.

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

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

Severe asthma: Patients with severe chronic asthma and those who are dependent on systemic corticosteroids for adequate control of symptoms. Many patients who are dependent on systemic corticosteroids for adequate control of symptoms may be able to reduce significantly or eliminate their requirement for oral corticosteroids when they are transferred to high dose inhaled beclometasone dipropionate.

DOSAGE & ADMINISTRATION

Beclometasone dipropionate inhaler is for oral inhalation use only. Patients should be given a starting dose of inhaled beclometasone dipropionate appropriate to the severity of their disease. The dose may then be adjusted

until control is achieved, or reduced to the minimum effective dose according to individual response.

Adults (including the elderly): The usual starting dose is 200 micrograms twice a day. In more severe cases the starting dose may need to increase to 600 to 800 micrograms per day which may then be reduced when the patient's asthma has stabilised. The total daily dose may be administered as two, three or four divided doses

Children: 50 to 100 micrograms should be given two, three or four times daily in accordance to the response. Alternatively, 100 micrograms or 200 micrograms twice daily should be given. The usual starting dose is 100 micrograms twice daily. Beclometasone 250 Inhaler is not recommended for children.

There is no need to increase the dose in patients with hepatic or renal impairment.

Beclometasone 250 HFA Inhaler: The usual starting dose is 200 micrograms twice a day. In more severe cases the starting dose may need to increase to 600 to 800 micrograms per day which may then be reduced when the patient's asthma has stabilised. The total daily dose may be administered as two, three or four divided doses.

SIDE EFFECT

Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. Possible systemic effects include Cushing's syndrome, Cushingoid features, and adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract, and glaucoma.

PRECAUTION

Patients should be instructed in the proper use of the inhaler, and their technique checked, to ensure that the

drug reaches the target areas within the lungs. They should also be made aware that Beclometasone inhaler has to be used regularly, every day, even when they are asymptomatic, for optimum benefit.

USE IN PREGNANCY AND LACTATION

There is inadequate evidence of safety in human pregnancy. Administration of corticosteroids to pregnant animals can cause abnormalities of fetal development including cleft palate and intra-uterine growth retardation.

The use of beclometasone dipropionate in mothers breast feeding their babies requires that the therapeutic benefits of the drug be weighed against the potential hazards to the mother and baby.

CONTRAINDICATION

Hypersensitivity to any of the components. Special care is necessary in patients with active or quiescent pulmonary tuberculosis.

STORAGE

The Inhaler should be stored below 30° C, protected from direct sunlight and heat. The canister should not be broken, punctured or burnt, even when apparently empty. Keep away from eyes. Keep out of reach of children.

HOW SUPPLIED

Each Inhaler delivers 200 puffs.

Manufactured by :

 **SQUARE PHARMACEUTICALS LTD.**
Dhaka Unit, Kalzokir, Gazipur
Bangladesh

0000000000