

# Azbec®

Beclometasone Dipropionate BP HFA Inhaler

## DESCRIPTION

**Azbec®** is a preparation of Beclometasone Dipropionate. Beclometasone Dipropionate is a corticosteroid which acts as a bronchodilator and provides effective anti-inflammatory action in the lungs and offers preventive background treatment of asthma. Severe asthma requires regular medical assessment as death may occur. Patients with severe asthma have constant symptoms and frequent exacerbations, with limited physical capacity, and PEF values below 60% predicted at baseline with greater than 30% variability, usually not returning entirely to normal after a bronchodilator. These patients will require high dose inhaled or oral corticosteroid therapy. Sudden worsening of symptoms may require increased corticosteroid dosage which should be administered under urgent medical supervision.

## INDICATIONS

- Mild asthma (PEF values greater than 80% predicted at baseline with less than 20% variability)
- Intermittent symptomatic bronchodilator asthma
- Moderate asthma (PEF values 60-80% predicted at baseline with 20-30% variability)
- Severe asthma (PEF values less than 60% predicted at baseline with greater than 30% variability)
- Patients with severe chronic asthma
- Prophylactic asthma medication

## DOSAGE & ADMINISTRATION

Administration should be by the inhaled route only. It should be taken regularly even when they are asymptomatic. The dose may then be adjusted until control is achieved or reduced to the minimum effective dose according to the individual response.

### Adults and children over 12 years of age

Patients should be given a starting dose of inhaled Beclometasone dipropionate according to the severity of their disease based on the following guidance:

- Mild asthma: 200 to 600 mcg per day in divided doses
- Moderate asthma: 600 to 1000 mcg per day in divided doses
- Severe asthma: Up to 1000 mcg per day in divided doses

### Children over 7 years of age:

Up to 200 mcg per day in divided doses.

The dose may then be adjusted until control is achieved or reduced to the minimum effective dose according to the individual response.

There are no data on the use of Beclometasone dipropionate in children aged under seven years.

### Hepatic & Renal impaired patient:

No need to adjust the dose in elderly patients or in those with hepatic or renal impairment.

## CONTRAINDICATIONS

Beclometasone dipropionate is contraindicated in patients with a history of hypersensitivity to any of its components

## SIDE EFFECTS

- Candidiasis
- Throat (thrush)
- Hoarseness or throat irritation
- Paradoxical bronchospasm
- Adrenal suppression
- Growth retardation in children
- Hypersensitivity reactions
- Decrease in bone mineral density
- Cataract and glaucoma

## PRECAUTION & WARNING

Beclometasone dipropionate inhaler is not for use in acute attacks but for routine long-term management. Patients' inhaler technique should be checked to make sure that aerosol actuation is synchronized with inspiration of breath for optimum delivery of the medicine to the lungs. Following introduction of inhaled Beclometasone dipropionate, withdrawal of systemic therapy should be gradual. Treatment with Beclometasone dipropionate should not be stopped abruptly.

## USE IN PREGNANCY & LACTATION

There is inadequate evidence of safety of Beclometasone dipropionate in human pregnancy. Administration of medicines during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus.

No specific studies examining the transference of Beclometasone dipropionate into the milk of lactating animals have been performed.

## PHARMACEUTICAL PRECAUTION

Keep away from light and wet place. Keep out of reach of children. Do not store above 25 °C. Do not refrigerate or freeze. The canister is pressurized. It must not be burnt, punctured or broken even when apparently empty. Do not expose to temperatures higher than 50 °C.

## PACKAGING

**Azbec® 100:** Each canister contains 200 metered doses, each actuation delivers Beclometasone Dipropionate BP 100 mcg.

**Azbec® 250:** Each canister contains 200 metered doses, each actuation delivers Beclometasone Dipropionate BP 250 mcg.

**SK+F**

Manufactured by

**ESKAYEF PHARMACEUTICALS LTD.**

TONGI, GAZIPUR, BANGLADESH

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