

# **Decomit<sup>®</sup>**

Inhaler

## **Description**

The active ingredient of Decomit Inhaler is Beclomethasone Dipropionate BP which is a synthetic halogenated corticosteroid with anti-inflammatory activity.

## **Indications**

Decomit Inhaler (Beclomethasone Dipropionate BP) given by inhalation has a potent anti-inflammatory action within the lungs without the side effects observed when steroids are administered systemically.

Decomit inhaler is indicated for the management of patients with bronchial asthma including :

- ◆ Patients whose asthma is becoming worse and is inadequately controlled by bronchodilator therapy alone
- ◆ Patients whose asthma is not controlled by the combined use of bronchodilator and Sodium Cromoglycate
- ◆ Patients with severe asthma being treated with systemic corticosteroids or synthetic or actual adrenocorticotrophic hormone (ACTH)

## **Dosage and Administration**

It may take 1-3 months to achieve maximum therapeutic benefit from any corticosteroid inhalation therapy. Patients should be given a starting dose of inhaled Beclomethasone Dipropionate that is appropriate for 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* : The usual recommended maintenance dose is 100-250 µg given three or four times a day. Alternatively, 200 - 500 µg given twice daily has been effective in some patients. In patients with severe asthma, it is advisable to start with 600 to 1000 µg a day and reduce the dose according

to the response of the patients. High dose (up to 2000 µg daily) may control asthmatics not adequately controlled with more conventional doses. In patients receiving doses of 1500 µg or more, adrenal suppression (though may not be clinically significant) may occur which should be balanced against the therapeutic advantages.

*Children* : The usual starting dose is 100 µg twice daily. Some patients may require 100 µg three to four times daily (or 200 µg twice daily). Total dose for children should not exceed 500 µg daily.

### **Contraindication**

Hypersensitivity to Beclomethasone is contraindicated, and special care is necessary in patients with active or quiescent pulmonary tuberculosis.

### **Precautions**

Patients should be instructed about proper use of the inhalers to ensure that the drug reaches the target areas within the lungs. They should also be made aware that Beclomethasone inhaler has to be used regularly for optimum benefit. Patients should be made aware of the prophylactic nature of therapy with Beclomethasone inhaler and that it should be taken regularly, even when they are asymptomatic.

The maximum daily administration of Beclomethasone inhaler should not exceed 1 mg. Significant reduction in plasma cortisone levels has been reported in patients who receive twice this amount.

### **Side Effects**

Candidiasis of the mouth and throat (thrush) occurs in some patients, the incidence of which is increased with doses greater than 400 µg Beclomethasone Dipropionate per day. Patients with high blood levels of *Candida* precipitins, indicating a previous infection, are most likely to develop this complication. Some patients may find it helpful to rinse their mouth thoroughly with water after using the inhaler. Symptomatic candidiasis can be treated with topical antifungal therapy whilst still continuing the Beclomethasone inhaler.

In some patients, inhaled Beclomethasone Dipropionate may cause hoarseness or throat irritation. It may be helpful to rinse mouth with water immediately after inhalation.

As with other inhalation therapy, the potential for paradoxical bronchospasm should be kept in mind. If it occurs, the preparation should be discontinued immediately and alternative therapy instituted.

### **Commercial Packs**

Decomit® 100 Inhaler : Each canister contains 200 metered doses, each containing 100 µg of Beclomethasone Dipropionate BP.

Decomit® 250 Inhaler : Each canister contains 200 metered doses, each containing 250 µg of Beclomethasone Dipropionate BP.