

120x140mm

Batatec®

(Beclomethasone Dipropionate)



COMPOSITION

Betatec 400 Rotacaps:

Each capsule contains:

Beclomethasone Dipropionate 400 mcg

Each delivered dose contains

Beclomethasone Dipropionate 360 mcg

DESCRIPTION

Beclomethasone Dipropionate is a synthetic glucocorticoid with a potent anti-inflammatory activity and weak mineralocorticoid activity. Beclomethasone Dipropionate given by inhalation has a potent anti-inflammatory action within the lungs but does not cause adverse systemic glucocorticoid effects at therapeutic doses.

INDICATIONS

Betatec Rotacaps are indicated for a wide range of patients with bronchial asthma. These include those:

- Whose asthma is poorly controlled by bronchodilators alone;
- Who are inadequately controlled by sodium cromoglycate in Best addition to bronchodilators;
- With severe asthma who are dependent on systemic duon corticosteroids, or adrenocorticotrophic hormone (ACTH) or its synthetic equivalent.

Betatec 100 and **Betatec 200** Rotacaps are particularly important for managing asthma in children because good control can be achieved without retardation of growth.

DOSAGE & ADMINISTRATION

BETATEC Rotacaps are for inhalation use only through the Rotahaler. For optimum results Rotacaps should be used regularly.

Adults

The contents of two 200 mcg (or one 400 mcg) Rotacap(s) twice daily is the usual maintenance dose. Alternatively, one 200 mcg Rotacap may be administered three or four times daily. Maximum dosage is 1600 mcg in a day.

Children

One 100 mcg Rotacap two, three or four times daily, according to the response. Alternatively, 200 mcg twice daily may be administered.

CONTRAINDICATIONS

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

WARNINGS & PRECAUTIONS

Patients should be made aware of the prophylactic nature of therapy with inhaled Beclomethasone and that it should be taken regularly. Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids. Possible systemic effects include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma. It is important therefore that the dose of inhaled corticosteroid is titrated to the

120x140mm

lowest dose at which effective control of asthma is maintained.

As with all inhaled corticosteroids, special care is necessary in patients with active or quiescent pulmonary tuberculosis. Children who are on immunosuppressant drugs are more susceptible to infections than healthy children. Chicken pox and measles for example can have a more serious or even a fatal course in children on immunosuppressant corticosteroids.

For transfer of patients being treated with oral

Corticosteroids: The transfer of oral steroid-dependent patients to Betatec Rotacaps and their subsequent management needs special care as recovery from impaired adrenocortical function, may take a considerable time. Gradual withdrawal of the systemic steroid is recommended. In these patients, the possibility of residual impaired adrenal response should always be considered in emergency (medical or surgical) and elective situations likely to produce stress and appropriate corticosteroid treatment considered.

Pregnancy

The use of Beclomethasone Dipropionate during pregnancy requires that the possible benefits of the drug be weighed against the possible hazards.

Lactation

In the dosages used for direct inhalation, there

is low potential for significant levels in breast milk.

ADVERSE EFFECT

Candidiasis of the mouth and throat (thrush). This may be relieved by gargling with water after inhalation.

Dosage and Instructions:

To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in a dry place. Protect from light.

PRESENTATION

Betatec Rotacaps

Alu Alu Blister Pack of 3 x 10's.

بیٹا تک®
(میکلو میڈیٹھا زون ڈائیکسیپروپائیونیٹ)

خوراک و ہدایات:

صرف مستند ڈاکٹر کے نسخے کے مطابق ہی دوا فروخت اور استعمال کی جائے۔

بچوں کی پہنچ سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔

خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

روٹا کپسولز کھانے کے لئے نہیں۔

صرف روٹا فلویا ریو لائزر کے ذریعے استعمال کریں۔

Manufactured by
HIGHNOON LABORATORIES LTD
17.5 KM, Multan Road, Lahore, Pakistan.
www.highnoon-labs.com

Item Code No. 00000000