PROPOSED PACKAGE INSERT FOR

BECLATE 50 / 100 / 200 / 250 HFA PACKAGE INSERT

SCHEDULING STATUS:

S3

PROPRIETARY NAME (AND DOSAGE FORM):

BECLATE 50 HFA (metered dose inhaler)

BECLATE 100 HFA (metered dose inhaler)

BECLATE 200 HFA (metered dose inhaler)

BECLATE 250 HFA (metered dose inhaler)

COMPOSITION:

BECLATE 50 HFA: Each actuation delivers beclomethasone dipropionate 50 mcg into the mouthpiece of the actuator.

BECLATE 100 HFA: Each actuation delivers beclomethasone dipropionate 100 mcg into the mouthpiece of the actuator.

BECLATE 200 HFA: Each actuation delivers beclomethasone dipropionate 200 mcg into the mouthpiece of the actuator.

BECLATE 250 HFA: Each actuation delivers beclomethasone dipropionate 250 mcg into the mouthpiece of the actuator.

Propellant: **BECLATE HFA** metered dose inhalers contain the propellant, HFA-134a.

PHARMACOLOGICAL CLASSIFICATION:

A 21.5.1. Corticosteroids and analogues.

PHARMACOLOGICAL ACTION:

Beclomethasone dipropionate is a synthetic glucocorticoid with anti-inflammatory action within the respiratory tract when given by inhalation.

INDICATIONS:

BECLATE HFA Inhalers are indicated for the prophylactic treatment of bronchospasm, in the following groups of patients with asthma:

1. Patients who are expected to be on long term steroid maintenance therapy.
2. Asthmatic patients poorly controlled by bronchodilators. In these patients **BECLATE HFA** may facilitate the control of the asthma and may reduce the need for bronchodilators.
3. Patients who are inadequately controlled by sodium cromogylcate in addition to bronchodilators.
4. Patients with severe asthma who are dependent on systemic corticosteroids, or those patients who are receiving intermittent courses of oral steroids.
5. Inhaled beclomethasone dipropionate is particularly important for managing asthma in children because effective control can be achieved without the retardation of growth commonly associated with systemic steroids.

CONTRA-INDICATIONS:

Hypersensitivity to any of the ingredients of this preparation.

Acute status asthmaticus.

Special care is necessary in patients with active or quiescent pulmonary tuberculosis.

Safety of **BECLATE HFA** in pregnancy has not been established.

WARNINGS:

Patients should be instructed in the proper use of the inhaler to ensure that the inhaled beclomethasone reaches the target area within the lungs. They should also be made aware of the prophylactic nature of therapy with inhaled beclomethasone dipropionate, and that it should be taken regularly even when they are asymptomatic. In patients who have been transferred to inhalation therapy, systemic steroid therapy may need to be re-instated rapidly during periods of stress or where airway obstruction or mucus prevents absorption from the inhalation.

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

Adrenal suppression may occur at standard doses of beclomethasone. In such patients, precautions should be taken to provide systemic corticosteroid cover in situations of prolonged stress.

Patients being treated with oral corticosteroids should be in a stable state before having **BECLATE HFA** added to their current therapy.

The transfer of patients who have received systemic steroids for long periods of time or at high doses, or both, to beclomethasone therapy and their subsequent management needs special care. Recovery from impaired adrenocortical function, caused by prolonged systemic steroid therapy, is slow. The patient should be in a reasonably stable state before being given **BECLATE HFA** in addition to the usual maintenance dose of systemic steroids. Withdrawal of the systemic steroid should be gradual, starting after about 7 days by reducing the daily oral dose by 1 mg prednisolone, or equivalent, at intervals not less than one week.

Adrenocortical function should be monitored regularly.

Most patients can be successfully transferred to **BECLATE HFA** with maintenance of good respiratory function, but special care is necessary for the first months after the transfer until the hypothalamic-pituitary-adrenal system has sufficiently recovered to enable the patient to cope with emergencies such as trauma, surgery and infections.

Patients who have been transferred to inhalation therapy should carry a warning card indicating that systemic steroid therapy may need to be reinstated without delay during periods of stress. It may be advisable to provide such patients with a supply of oral steroids to use in emergency, for example when the asthma worsens as a result of chest infection. The dose of **BECLATE HFA** should be increased at this time and then gradually reduced to the maintenance level after the systemic steroid has been discontinued.

Discontinuation of systemic steroids may cause exacerbation of allergic diseases such as atopic eczema and rhinitis. These should be treated symptomatically as required.

It must be explained to patients that **BECLATE HFA** inhalers are not for symptomatic relief of bronchospasm and that they must not expect rapid relief of asthma attacks with **BECLATE HFA**. **BECLATE HFA** has to be inhaled at the recommended dosage at regular intervals, and the patient should be informed that benefit may take several days to become apparent.

An inhaled short-acting bronchodilator is required for the relief of acute asthmatic symptoms and patients should be advised to have such rescue medication available at all times.

Regular use (more than 2-3 times per week) or increasing use of bronchodilators to relieve acute symptoms indicates deterioration of asthma control. Patients must be instructed to consult their physician if they find that their relief bronchodilator treatment (rescue medication) becomes less effective or they need more inhalations than usual. These patients

should be assessed and consideration given to the need for increasing anti-inflammatory therapy (i.e. increasing the dose of inhaled corticosteroids or a course of oral steroids).

DOSAGE AND DIRECTIONS FOR USE:

Do not exceed the recommended dose.

BECLATE HFA inhalers are for oral inhalation use only. An appropriate spacer device (Zerostat spacer or Cipla Medpro spacer) should be used in patients who struggle to coordinate aerosol actuation with inspiration of breath.

The initial dose of **BECLATE HFA** should be appropriate to the severity of the asthma. The dose is then adjusted until control is achieved, or reduced to the minimum effective dose according to the individual patient's response.

Adults: The usual dose is 200 µg twice daily. In more severe cases the dosage may be started at or increased to 600-800 µg per day and subsequently reduced when the patient's asthma has stabilised.

The totaly daily dose may be administered as two, three or four divided doses. In patients with severe asthma, or those showing only partial response to standard inhalation doses, high dose inhalation therapy may be considered, and doses of up to 1 mg daily, in divided doses, may be used.

Maximum daily dose: 1 000 µg (1 mg) daily.

Children: 50-100 µg should be given two, three or four times daily according to the age and response. Alternatively, 100 µg or 200 µg twice daily may be administered.

Maximum daily dose: 500 µg daily.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side Effects:

Incidence Terminology:

Common:	≥ 1% of patients
Uncommon:	≥ 0.1% and < 1%
Rare:	≥ 0.01% and < 0.1
Very rare:	< 0.01%

Undetermined: the frequency of incidence has not been determined

(frequent or less frequent if incidence is not known)

Body as a whole:

Undetermined

Hematological:

Undetermined

Gastrointestinal:

Undetermined

Kidney/Genitourinary:

Undetermined

Metabolic and nutritional:

Common:	Intolerance to adrenocortocoids
Uncommon:	Reduction of cortisol levels

Musculoskeletal System:

Undetermined

Respiratory System:

Uncommon:	Hoarseness of voice or throat irritation

Skin:

Common: Rashes and urticaria

Other:

Common: Hypersensitivity reactions (including erythema, oedema of the eyes, face, lips and throat, pruritus)

Special Precautions:

Special care is necessary in patients with active or quiescent pulmonary tuberculosis and the therapeutic advantages should be weighed against possible undesirable effects. Candidiasis of the mouth and throat (thrush) occurs in some patients, the incidence of which is increased with doses greater than 400 µg 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 inhalation. The water should not be swallowed. The use of an appropriate spacer may also be considered.

If respiratory infection occurs during treatment with **BECLATE HFA**, antibacterial treatment should be commenced, and the administration of oral steroids may have to be considered.

Systemic effects of inhaled corticosteroids may occur, particularly if high doses are used for prolonged periods of time. These can include adrenal suppression, decrease in bone mineral density, cataract, glaucoma and growth retardation in children and adolescents. It is therefore important to titrate the dose of inhaled steroids to the lowest dose at which effective control of the patient's asthma is maintained. The height of children on long-term inhaled corticosteroids should be regularly monitored. If growth retardation is suspected, referral to a paediatric respiratory specialist and possible review of the dose should be considered.

As with other inhalation therapy, paradoxical bronchospasm may occur, presenting with an immediate increase in wheezing after inhalation. Immediate treatment with a short-acting inhaled bronchodilator should be instituted. **BECLATE HFA** should be discontinued, and alternative prophylactic treatment instituted if necessary. Due to the risk of severe exacerbations or even death, patients with asthma, especially severe asthma, require regular medical assessment, including lung function testing.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

The only harmful effect that follows inhalation of large amounts of the drug over a short time-period is suppression of hypothalamic-pituitary-adrenal (HPA) function. No special emergency action need be taken. Treatment should be continued at the recommended dose. HPA function recovers in a day or two. In the event of excessive intake of beclomethasone for a long period of time a degree of adrenal suppression could occur in addition to suppression of HPA function. The patient should be treated as steroid dependent and transferred to a suitable maintenance dose of systemic steroids.

IDENTIFICATION:

A solution filled in an aluminium container in a CFC-free propellant gas. The aluminium container is fitted with a metering valve and fitted in a plastic oral adaptor. Each canister is clearly labelled **BECLATE HFA 50**, **BECLATE HFA 100**, **BECLATE HFA 200** or **BECLATE HFA 250**.

PRESENTATION:

BECLATE HFA 50: A pressurised aluminium canister fitted with a metered dispensing valve crimped in place and a plastic oral adaptor. Each canister provides 200 metered inhalations.

BECLATE HFA 100: A pressurised aluminium canister fitted with a metered dispensing valve crimped in place and a plastic oral adaptor. Each canister provides 200 metered inhalations.

BECLATE HFA 200: A pressurised aluminium canister fitted with a metered dispensing valve crimped in place and a plastic oral adaptor. Each canister provides 200 metered inhalations.

BECLATE HFA 250: A pressurised aluminium canister fitted with a metered dispensing valve crimped in place and a plastic oral adaptor. Each canister provides 200 metered inhalations.

STORAGE INSTRUCTIONS:

BECLATE HFA inhalers should be stored at room temperature at or below 25 °C, and should not be refrigerated. Avoid storage in direct sunlight or heat. The canister is pressurised. It should not be broken, punctured or burnt, even when apparently empty.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:

Beclate 50 HFA - 38/21.5.1/0186

Beclate 100 HFA - 37/21.5.1/0652

Beclate 200 HFA - 37/21.5.1/0653

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

CIPLA-MEDPRO (PTY) LTD.,

Building 9, Parc du Cap,

Mispel Street, Belville,

7530, South Africa

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23 September 2005