PACKAGE INSERT FOR

BUDEFLAM-100 METERED DOSE INHALER

BUDEFLAM-200 METERED DOSE INHALER:

SCHEDULING STATUS:

S3

PROPRIETARY NAME (AND DOSAGE FORM):

BUDEFLAM-100 (Metered dose Inhaler)

BUDEFLAM-200 (Metered dose Inhaler)

COMPOSITION:

BUDEFLAM-100 Metered dose Inhaler: is a metered dose, pressurised inhaler which delivers 100 micrograms budesonide per actuation.

BUDEFLAM-200 Metered dose Inhaler: is a metered dose, pressurised inhaler which delivers 200 micrograms budesonide per actuation.

PHARMACOLOGICAL CLASSIFICATION:

A 21.5.1 Corticosteroids and analogues.

PHARMACOLOGICAL ACTION:

Budesonide is a non-halogenated corticosteroid, which, when inhaled, has a local anti-inflammatory action in the lungs. Budesonide is rapidly inactivated by the liver.

INDICATIONS:

Prophylaxis of the symptoms of asthma.

CONTRA-INDICATIONS:

Hypersensitivity to budesonide.

BUDEFLAM is contra-indicated in patients with active or quiescent pulmonary tuberculosis and in other untreated airway infections of bacterial, fungal or viral origin.

WARNINGS:

Patients should be carefully instructed in the correct use of the inhaler, making sure that the inhaler activation is synchronised with inspiration. Patients should also be made aware of the prophylactic nature of inhaled budesonide therapy, and that it should be taken, even when they are asymptomatic.

Adrenal suppression may occur.

Bacterial and fungal (including Candida) infections of the mouth and throat may occur. Patients with high blood levels of Candida precipitants, 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.

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Shake before use.

Adults and children over 12 years of age:

Initial dose: 400 µg daily in divided doses.

In patients whose asthma is not responding to low dose budesonide therapy, or when the patient's asthma can no longer be controlled by the maximum maintenance dose of

bronchodilators, the daily dosage may be increased to up to 1600 micrograms.

In controlled patients, twice daily administration may be adequate.

THE MAINTENANCE DOSE SHOULD BE INDIVIDUALISED AND SHOULD BE THE LOWEST POSSIBLE DOSAGE.

Children (5 years and older):

The usual dose is 50 - 200 µg twice daily. In severe asthma, the dose the dose may be increased to a total daily dose of 800 µg.

THE MAINTENANCE DOSE SHOULD BE INDIVIDUALISED AND SHOULD BE THE LOWEST POSSIBLE DOSAGE.

Patients on concomitant therapy with inhaled bronchodilators should use the bronchodilators several minutes before the inhalation of **BUDEFLAM** to minimise the possible local side-effects, such as cough.

The use of a spacer device is recommended when the daily dose exceeds 400 µg in adults, and for all doses in children. This will improve lung deposition and will reduce the systemic absorption of budesonide.

Rinse the mouth after each dosage administration.

Treatment with inhaled steroids should not be stopped abruptly.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects:

Endocrine/Metabolic disorders:

Less Frequent: Although short-term growth may be affected, there is no

evidence that any significant effect on the height is produced by inhaled corticosteroids.

Neuropsychiatric disorders:

Frequent: Psychotic behaviour. This may include nervousness, restlessness and depression.

Less Frequent: Headache.

Eye disorders:

Less Frequent: Cataract formation after prolonged use.

Ear, nose and throat disorders:

Frequent: Dysphonia. Candida albicans infections of the mouth and throat, dryness of mouth and throat, bad taste.

It may be helpful to rinse the mouth with water after the inhaler has been used.

Respiratory disorders:

Frequent: Local irritation and paradoxical bronchoconstriction. Pulmonary infiltrates with eosinophilia may occur.

Gastrointestinal disorders:

Less Frequent: Nausea and diarrhoea.

Skin and subcutaneous tissue disorders*:*

Frequent: Skin thinning and purpura. Other skin reactions may include urticaria, rashes and dermatitis.

General disorders*:*

Less Frequent: Tiredness and thirst.

Special Precautions:

Transfer of patients, dependent upon oral steroids, to treatment with budesonide demands special care, and is preferably done when the patient is in a relatively stable phase. Budesonide should be given in combination with the previously used oral steroid dose for about ten days. After this period of time, reduction of the oral corticosteroid can be started with a dose reduction corresponding to about 1 mg prednisolone per day per week. Some patients may experience uneasiness during the withdrawal period, due to decreased steroid effect. Acute exacerbations, accompanied by increased mucous viscosity and mucous plugging may require complementary treatment with an oral corticosteroid. It is important to monitor intercurrent infections and treat them appropriately.

Appropriate measures should be taken to protect the patient against stress situations, e.g. severe infections, surgery. Treatment with inhaled steroids should not be stopped abruptly.

Some patients may experience uneasiness during the withdrawal period due to a decreased steroid effect. The physician may have to explain the reason for BUDEFLAM treatment in order to encourage the patient to continue. The length of time needed for the body to regain its natural production of corticosteroid in sufficient amounts is often extensive. Thus, during physically stressing situations such as severe infections, trauma and surgical operations, it will be necessary to give the patients an additional oral steroid

dose. Acute exacerbations, accompanied by increased mucous viscosity and mucous plugging may require complementary treatment with an oral corticosteroid.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

(see "**SIDE-EFFECTS AND SPECIAL PRECAUTIONS**").

Treatment with budesonide inhaler should be continued at the recommended dose to control the asthma and appropriate measures taken to protect the patient against stress situations.

Treatment is symptomatic and supportive.

IDENTIFICATION:

BUDEFLAM-100:	A milky white homogeneous suspension filled in an aluminium container in CFC free propellent gas. The aluminium container is fitted with a metering valve and plastic oral adaptor labelled as **BUDEFLAM-100**.
BUDEFLAM-200:	A milky white homogeneous suspension filled in an aluminium container in CFC free propellent gas. The aluminium container is fitted with a metering valve and plastic oral adaptor labelled as **BUDEFLAM-200**.

PRESENTATION:

Both **BUDEFLAM-100** (100 µg/actuation) and **BUDEFLAM-200** (200 µg/actuation) are presented in a seamless aluminium canister with a metered dispensing valve crimped in place, and a mouthpiece attached.

Each canister of **BUDEFLAM-100** and **BUDEFLAM-200** provides 300 metered inhalations.

STORAGE INSTRUCTIONS:

Store below 30°C.

Avoid storage in direct sunlight or heat. The canister should not be punctured, broken or burnt even if it is apparently empty.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:

BUDEFLAM-100: 30/21.5.1/0255

BUDEFLAM-200: 32/21.5.1/0115

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

CIPLA MEDPRO (PTY) LTD.

Rosen Heights,

Pasita Street

Rosen Park

Bellville

7530

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