BUDESONIDE

ASMAVENT®

250 mcg/mL NEBULIZING SUSPENSION
Anti-Asthma

Formulation:
Each mL contains 250 mcg of Budesonide.

Indication:
Budesonide is a glucocorticoid used by inhalation for the maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years of age.

Mechanism of Action:
An anti-inflammatory corticosteroid that exhibits potent glucocorticoid activity and weak mineralocorticoid activity. Corticosteroids have been shown to have a wide range of inhibitory activities against multiple cell types (e.g. mast cells, eosinophils, neutrophils, macrophages and lymphocytes) and mediators (e.g. histamine, eicosanoids, leukotrienes, and cytokines) involved in allergic and non-allergic-mediated inflammation. The anti-inflammatory actions may contribute to their efficacy in asthma.

Dosage and Administration:
The usual adult dose is 1000 mcg to 2000 mcg inhaled twice daily with a maintenance dose of 500 mcg to 1000 mcg inhaled twice daily. The initial dose for children is 500 mcg to 1000 mcg inhaled twice daily with a maintenance dose of 250 mcg to 500 mcg twice daily. Or as prescribed by a physician. This is administered by the use of a nebulizer.

Contraindications:
Hypersensitivity to Budesonide.

Precautions:
Inhaled corticosteroids may cause a reduction in growth velocity to pediatric patients. Because Budesonide is absorbed into the circulation and may be systemically active, particularly at high doses, suppression of hypothalamic-pituitary-adrenal (HPA) function may be associated when Budesonide is administered at doses exceeding those recommended.

Particular care should be taken when given to patients post-operatively or during periods of stress for evidence of inadequate adrenal response.

It should be used only with great caution in the presence of congestive heart failure or hypertension, in patients with diabetes mellitus, epilepsy, glaucoma, infectious diseases, ocular herpes simplex, chronic renal failure and uremia, and in elderly patients.

During long courses of corticosteroid therapy, patients should be examined regularly, and monitored for hypertension, glycosuria, hypokalemia, gastric discomfort and mental changes.

Systemic corticosteroid effects such as hypercorticism and adrenal suppression may appear in a small number of patients particularly at higher dose. If these occur, Budesonide should be reduced slowly, consistent with accepted procedures for management of asthma symptoms and for tapering of systemic corticosteroids.

Adverse Drug Reactions:

1. Disturbance of electrolyte balance manifested as sodium and water retention, edema, hypertension and hypokalemic alkalosis.
2. Increased susceptibility to all kinds of infections.
3. Acute adrenal insufficiency may occur during prolonged treatment or on cessation of treatment and may be precipitated by stressful situations.
4. Growth retardation in children has also been reported.
5. High doses of corticosteroids administered during pregnancy may cause fetal or neonatal adrenal suppression.

Drug Interactions:
Reduced efficacy has been noted in patients who also received phenytoin or phenobarbitone. Rifampicin generally reduces the activity of corticosteroids.
Ketoconazole, a potent inhibitor of cytochrome P450 3A, may increase plasma levels of Budesonide during concomitant dosing.

Caution:
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription

Storage Condition:
Store at temperatures not exceeding 30°C.

Availability:
5 ampoules x 2 mL/foil pouch (box of 6 foil pouches)

DRP-6604-01

Manufactured by:
EURO-MED® LABORATORIES PHIL., INC.
Km. 36 Gen. Emilio Aguinaldo Highway, Dasmariñas, Cavite, Philippines
Distributed by:
UNITED LABORATORIES, INC.
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines
Under Authority by:
UNILAB, Inc.
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines

Reg. IPOPHIL PED157026IN01