# Aeronid®

Inhaler

## Description

Budesonide BP, the active ingredient of Aeronid inhaler, is a 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, oeosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in allergic and non-allergic inflammation. These anti-inflammatory actions of Budesonide contribute to its efficacy in asthma.

## Indications

Aeronid inhaler is indicated for the maintenance treatment of asthma as prophylactic therapy in adult and paediatric patients six years of age or older. It is also indicated for patients requiring oral corticosteroid therapy for asthma, many of those patients may be able to reduce or eliminate their requirement for oral corticosteroids over time.

Aeronid inhaler is NOT indicated for the relief of acute bronchospasm.

## Dosage and Administration

Aeronid inhaler should be administered by the orally inhaled route in asthmatic patients age 6 years and older. Individual patients will experience a variable onset and degree of symptom relief. Generally, Aeronid inhaler has a relatively rapid onset of action for an inhaled corticosteroid. Improvement in asthma control following inhaled administration of Aeronid inhaler can occur within 24 hours of initiation of treatment, although maximum benefit may not be achieved for 1 to 2 weeks, or longer. The safety and efficacy of Aeronid inhaler when administered in excess of recommended doses have not been established.

The recommended starting dose and the highest recommended dose of Aeronid inhaler, based on prior asthma therapy, are listed in the following table :

| | Previous Therapy | Recommended Starting Dose | Highest Recommended Dose |
|---|---|---|---|
| **Adults:** | Bronchodilators alone | 200 to 400 µg twice daily | 400 µg twice daily |
| | Inhaled Corticosteroids* | 200 to 400 µg twice daily | 800 µg twice daily |
| | Oral Corticosteroids | 400 to 800 µg twice daily | 800 µg twice daily |
| **Children:** | Bronchodilators alone | 200 µg twice daily | 400 µg twice daily |
| | Inhaled Corticosteroids* | 200 to 400 µg twice daily | 400 µg twice daily |
| | Oral Corticosteroids | The highest recommended dose in children is 400 µg twice daily | |

*In patients with mild to moderate asthma who are well controlled on inhaled corticosteroids, dosing with Aeronid inhaler 200 µg or 400 µg once daily may be considered. Aeronid inhaler can be administered once daily either in the morning or in the evening.

If the once daily treatment with Aeronid inhaler does not provide adequate control of asthma symptoms, the total daily dose should be increased and/or administered in divided doses.

*Patients maintained on chronic oral corticosteroids*

Initially, Aeronid inhaler should be used concurrently with the patient's usual maintenance dose of systemic corticosteroid. After approximately one week, gradual withdrawal of the systemic corticosteroid is started by reducing the daily or alternate daily dose. The next reduction is made after an interval of one or two weeks, depending on the response of the patient. Generally, these decrement should not exceed 2.5 mg of Prednisone or its equivalent. A slow rate of withdrawal is strongly recommended. During reduction of oral corticosteroids, patients should be carefully monitored for asthma instability, including objective measures of airway function, and for adrenal insufficiency. During withdrawal, some patients may experience symptoms of systemic corticosteroid

withdrawal, e.g., joint and/or muscular pain, lassitude and depression, despite maintenance or even improvement in pulmonary function. Such patients should be encouraged to continue with Aeronid Inhaler but should be monitored for objective signs of adrenal insufficiency. If evidence of adrenal insufficiency occurs, the systemic corticosteroid dose should be increased temporarily and thereafter withdrawal should be continued more slowly. During periods of stress or a severe asthma attack, transferred patients may require supplementary treatment with systemic corticosteroids.

**Contraindications**

Budesonide inhalation aerosol is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.

Hypersensitivity to Budesonide contraindicates the use of Aeronid inhaler.

**Precautions**

During withdrawal from oral corticosteroids, some patients may experience symptoms of systemically active corticosteroid withdrawal, e.g., joint and/or muscular pain, lassitude, and depression, despite maintenance or even improvement of respiratory function.

Aeronid inhaler will often permit control of asthma symptoms with less suppression of hypothalamic-pituitary-adrenal (HPA) function than therapeutically equivalent oral doses of Prednisone. Since Budesonide is absorbed into the circulation and can be systemically active at higher doses, the full beneficial effects of Aeronid inhaler in minimising HPA dysfunction may be expected only when recommended dosages are not exceeded and individual patients are titrated to the lowest effective dose. Since individual sensitivity to effects on cortisol production exists, physicians should consider this fact when prescribing Aeronid inhaler.

Because of the possibility of systemic absorption of inhaled corticosteroids, patients treated with these drugs should be observed carefully for any evidence of systemic corticosteroid effects. Particular care should be taken in observing patients postoperatively or during periods of stress for evidence of inadequate adrenal response.

It is possible that systemic corticosteroid effects such as hypercorticism and adrenal suppression may appear in a small number of patients, particularly at higher doses. If such changes occur, Aeronid inhaler should be reduced slowly, consistent with accepted procedures for management of asthma symptoms and for tapering of systemic steroids.

A reduction of growth velocity in children or teenagers may occur as a result of inadequate control of chronic diseases such as asthma or from use of corticosteroids for treatment. Physicians should closely follow the growth of all paediatric patients taking corticosteroids by any route and weigh the benefits of corticosteroid therapy and asthma control against the possibility of growth suppression.

Although patients in clinical trials have received Aeronid inhaler on a continuous basis for periods of 1 to 2 years, the long term local and systemic effects of Aeronid inhaler in human subjects are not completely known.

In clinical trials with Aeronid inhaler, localised infections with *Candida albicans* occurred in the mouth and pharynx in some patients. If oropharyngeal candidiasis develops, it should be treated with appropriate local or systemic (i.e., oral) antifungal therapy while still continuing with Aeronid inhaler therapy, but at times therapy with Aeronid inhaler may need to be temporarily interrupted under close medical supervision.

Inhaled corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infection of the respiratory tract, untreated systemic fungal, bacterial, viral or parasitic infections; or ocular herpes simplex.

Rare instances of glaucoma, increased intraocular pressure, and cataracts have been reported following the administration of inhaled corticosteroids.

**Side Effects**

The following adverse reactions were reported in patients treated with Aeronid inhaler.

*General* : Headache, flu-like syndrome, pain, back pain, fever, neck pain, asthenia.

*Respiratory system* : Respiratory tract infections, pharyngitis, sinusitis, rhinitis, voice alteration, cough aggravation.

*Digestive system* : Oral candidiasis, dyspepsia, gastroenteritis, nausea, abdominal pain, dry mouth, vomiting.

*Metabolic and nutritional* : Weight gain.

*Musculoskeletal* : Fracture, myalgia, arthralgia.

N*ervous system* : Syncope, hypertonia, migraine.

*Skin* : Ecchymosis.

*Psychiatric* : Insomnia.

*Resistance Mechanisms* : Infection.

*Special Senses* : Taste perversion.

*Paediatric studies :* There were no clinically relevant differences in the pattern or severity of adverse events in children compared with those reported in adults.

*Adverse event reports from other sources* : Rare adverse events reported include immediate and delayed hypersensitivity reactions including rash, contact dermatitis, urticaria, angio-oedema and bronchospasm; symptoms of hypocorticism and hypercorticism; psychiatric symptoms including depression, aggressive reactions, irritability, anxiety and psychosis.

**Commercial Packs**

Aeronid® 200 Inhaler : Each canister contains 200 metered doses, each containing 200 µg Budesonide BP.