

Steradin[®] HFA

Inhalation Aerosol

Beclomethasone dipropionate BP

Description

The active component of **Steradin[®]** HFA inhaler is a preparation of beclomethasone dipropionate which is an environment friendly inhaler which does not contain chlorofluorocarbons (CFCs) as propellant. It is a diester of beclomethasone, a synthetic corticosteroid chemically related to dexamethasone. Beclomethasone dipropionate is an anti-inflammatory corticosteroid. Corticosteroids have multiple anti-inflammatory effects, inhibiting both inflammatory cells and release of inflammatory mediators. It is presumed that these anti-inflammatory actions play an important role in the efficacy of beclomethasone dipropionate in controlling symptoms and improving lung function in asthma. Inhaled beclomethasone dipropionate probably acts topically at the site of deposition in the bronchial tree after inhalation.

Indications and Usage

Steradin[®] HFA inhaler is indicated in the maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older. **Steradin[®]** HFA inhaler is also indicated for asthma patients who require systemic corticosteroid administration, where adding **Steradin[®]** HFA inhaler may reduce or eliminate the need for the systemic corticosteroids. Beclomethasone dipropionate is not indicated for the relief of acute bronchospasm.

Dosage and Administration

Steradin[®] HFA inhaler is administered by the inhaled route only. The recommended dosage guidelines of **Steradin[®]** HFA inhaler are given below:

Adults and Children Over 12 Years of Age

Mild Asthma: 200 to 600 mcg per day in divided doses.

Moderate Asthma: 600 to 1,000 mcg per day in divided doses.

Severe Asthma: 1000 to 2,000 mcg per day in divided doses.

The dose may then be adjusted until control is achieved, or reduced to the minimum effective dose according to the individual response.

Children Over 4 Years of Age

Up to 400 mcg per day in divided doses.

It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroid is regularly monitored.

Contraindications

Beclomethasone dipropionate inhaler should not be used in patients with known hypersensitivity to Beclomethasone dipropionate or any of the components of the preparation. Beclomethasone dipropionate is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required; and special care is necessary in patients with active or quiescent pulmonary tuberculosis.

Pregnancy and lactation

Beclomethasone dipropionate is pregnancy Category C. Like other corticosteroids, parenteral beclomethasone dipropionate was teratogenic and embryocidal in the mouse and rabbit when given at a dose of 0.1 mg/kg/day in mice or at a dose of 0.025 mg/kg/day in rabbits. These doses in mice and rabbits were approximately one-half the maximum recommended daily inhalation dose in adults on a mg/m² basis. No teratogenicity or embryocidal effects were seen in rats when exposed to an inhalation dose of 15 mg/kg/day (approximately 190 times the maximum recommended daily inhalation dose in adults on a mg/m² basis). There are no adequate and well controlled studies in pregnant women. Beclomethasone dipropionate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Corticosteroids are secreted in human milk. Because of the potential for serious adverse reactions in nursing infants from Beclomethasone dipropionate, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Precautions

Patients should be instructed on the proper use of the inhalers to ensure that the drug reaches the target areas within the lungs. They should also be made aware that Beclomethasone dipropionate HFA inhaler has to be used regularly for optimum benefit. Patients should be made aware of the prophylactic nature of therapy with Beclomethasone dipropionate HFA inhaler and that it should be taken regularly, even when they are asymptomatic. The maximum daily administration of Beclomethasone dipropionate HFA inhaler should not exceed 1mg (1000 mcg). Significant reduction in plasma cortisol levels has been reported in patients who receive twice this amount.

Side Effects

Beclomethasone dipropionate HFA inhalation aerosol has been found generally well tolerated in the extensive clinical development program. The adverse effects that occurred in a very few patients are headache, pharyngitis, URTI, rhinitis, sinusitis, pain, back pain, nausea, dysphonia etc. No patients in the clinical development program developed symptomatic oropharyngeal candidiasis with HFA beclomethasone. If it occurs, it can be treated with topical antifungal therapy whilst still continuing with the Beclomethasone dipropionate HFA inhaler. In some patients, inhaled beclomethasone dipropionate may cause hoarseness or throat irritation. It may be helpful to rinse mouth with water immediately after inhalation. As with other inhalation therapy, the potential for paradoxical bronchospasm should be kept in mind. If it occurs, the preparation should be discontinued immediately and alternative therapy instituted.

Drug interaction

There are no known drug interactions of Beclomethasone inhaler.

Overdosage

Acute: Inhalation of the drug in doses in excess of those recommended may lead to temporary suppression of adrenal function. This does not necessitate emergency action to be taken.

Chronic: Use of inhalation in excess of 1500 mg per day over prolonged periods may lead to some degree of adrenal suppression.

Pharmaceutical Precaution

Do not puncture, break or incinerate pressurized canister even when apparently empty.

Avoid storage in direct sunlight or heat.

Store below 30°C.

Keep away from eyes.

Keep away from children.

Package quantities

Steradin[®] 250 HFA Inhaler: Each canister contains 200 metered doses, each containing 200 mcg of beclomethasone dipropionate BP. It does not contain CFC as propellant.

Steradin[®] 100 HFA Inhaler: Each canister contains 200 metered doses, each containing 100 mcg of beclomethasone dipropionate BP. It does not contain CFC as propellant.

Steradin® 50 HFA Inhaler: Each canister contains 200 metered doses, each containing 50 mcg of beclomethasone dipropionate BP. It does not contain CFC as propellant.

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