Airfors

HFA Inhaler

Salbutamol Sulfate BP & Budesonide BP

Composition

Airfors 90/80 HFA Inhaler: Each actuation delivers Salbutamol (as Salbutamol Sulfate BP) 90 µg and Budesonide BP 80 µg.

Pharmacology

Airfors HFA Inhaler HFA inhaler is a combination of Sulbutamol Sulphate BP and Budesonide BP. It is a Hydrofluoroalkane (HFA) based environment friendly inhaler as it does not contain Chlorofluorocarbon (CFC) as propellant which is one of the main reasons of ozone layer depletion. Sulbutamol activates beta2-adrenergic receptors on airway smooth muscle which leads to the activation of adenyl cyclase and increases intracellular concentration of cyclic-3',5'-adenosine monophosphate (cyclic AMP). Then it activates protein kinase A, which inhibits the phosphorylation of myosin and lowers intracellular ionic calcium concentrations, resulting in relaxation. Budesonide is an anti-inflammatory corticosteroid that exhibits potent glucocorticoid activity and weak mineralocorticoid activity.

Indications

Airfors HFA Inhaler is indicated for the as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in patients with asthma 18 years of age and older..

Dosage and Administration

Route of Administration: HFA Inhalation Aerosol

The recommended dosage is 2 actuations of **Airfors** HFA Inhaler as needed for asthma symptoms by oral inhalation. Do not take more than 6 doses (12 inhalations) in a 24-hour period.

OR AS DIRECTED BY THE PHYSICIAN.

Contraindications

Airfors HFA Inhaler is contraindicated in patients with a history of hypersensitivity to Salbutamol, Budesonide, or any of the excipients.

Warning & Precautions

- If **Airfors** HFA Inhaler produce paradoxical bronchospasm, it should be discontinued immediately and alternative therapy should be instituted
- **Airfors** HFA Inhaler can produce cardiovascular effects in some patients as measured by increases in pulse rate, blood pressure, and/or other symptoms. If such effects occur, **Airfors** HFA Inhaler may need to be discontinued
- **Airfors** HFA Inhaler should not be used more than the maximum daily dose as an overdose may result
- Hypersensitivity reactions can occur after administration of **Airfors** HFA Inhaler such as anaphylaxis, angioedema, bronchospasm, oropharyngeal edema, rash and urticaria. Discontinue **Airfors** HFA Inhaler if such reactions occur
- Beta-adrenergic agonist medicines may produce significant hypokalemia in some patients
- Inhaled corticosteroids should be used with caution in patients. It may produce active or quiescent tuberculosis infection of the respiratory tract, systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex
- **Airfors** HFA Inhaler contains budesonide, an inhaled corticosteroid (ICS) which can cause infections of the mouth and pharynx with Candida Albicans. When such an infection develops, it should be treated with appropriate local or systemic antifungal therapy while treatment with **Airfors** continues.
- Patients treated with **Airfors** HFA Inhaler should be observed carefully for any evidence of systemic corticosteroid effects
- Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing ICS
- Glaucoma, increased intraocular pressure, and cataracts have been reported following the long-term administration of ICS, including budesonide. Referral should be considered to an ophthalmologist in patients who develop ocular symptoms
- Caution should be exercised when considering the co-administration of **Airfors**HFA Inhaler with long-term ketoconazole and other known strong CYP3A4 inhibitors (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, telithromycin)
- If the patient continues to experience symptoms after using **Airfors** or requires more doses of **Airfors** HFA Inhaler than usual and requires evaluation of the patient with their treatment regimen

Side Effects

Common side effects: Headache, cough, hoarseness, thrush in mouth and throat, adrenal insufficiency, allergic reactions, low bone mineral density, eye problems including glaucoma, cataracts etc.

Use in Pregnancy & Lactation

It is not known that if **Airfors** HFA Inhaler may harm the unborn baby. There are no available data on the effects of **Airfors** HFA Inhaler on the breastfed child or on milk production. Administration of **Airfors** HFA Inhaler in pregnant and lactating women should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus

Drug Interaction

- Strong cytochrome P4503A4 inhibitors (e.g. ritonavir)
- Other short-acting bronchodilators: Use judiciously with other short-acting beta agonists
- Beta blockers: May decrease effectiveness of **Airfors** HFA Inhaler and produce severe bronchospasm
- Diuretics, or non-potassium-sparing diuretics: May potentiate hypokalemia or ECG changes. Consider monitoring potassium levels with concomitant use
- Digoxin: May decrease serum digoxin levels
- Monoamine oxidase inhibitors (MAOI) and tricyclic antidepressants: Use **Airfors** HFA Inhaler with extreme caution with concomitant use

Packing

Airfors 90/80 HFA Inhaler: Each canister contains 120 metered doses, each dose contains Salbutamol (as Salbutamol Sulfate BP) 90 µg and Budesonide BP 80 µg.

Pharmaceutical Precautions

- Do not puncture, break or incinerate the pressurized canister even when apparently empty.
- Avoid storage in direct sunlight and heat.
- Store below 30° C. temperature & dry place, protected from light.
- Keep away from children.
- Keep away from eyes.

***Further information is available on request.**

ENVIRONMENT FRIENDLY

CFC FREE

Manufactured by

The ACME Laboratories Ltd.

Dhulivita, Dhamrai, Dhaka, Bangladesh

For Health, Vigour and Happiness