

Composition:

Beclocort®-50 HFA inhaler: Each puff delivers Bedometasone Dipropionate BP 50 µg.

Beclocort®-100 HFA inhaler: Each puff delivers Bedometasone Dipropionate BP 100 µg.

Beclocort®-250 HFA inhaler: Each puff delivers Bedometasone Dipropionate BP 250 µg.

Pharmacology:

Bedometasone Dipropionate is a synthetic glucocorticoid. It has many important functions, including control of inflammatory responses. When Bedometasone is inhaled into the lungs, it is absorbed into the cells of the lungs and airways. By preventing the inflammation and excess mucus formation, Bedometasone makes it easier to breathe and helps prevent asthma attacks. Use of Bedometasone inhaler also reduces the potential for side effects occurring in other parts of the body, as the amount absorbed into the blood through the lungs is lower than if it is taken by mouth.

Indication:

Beclocort® HFA inhaler is indicated in the maintenance treatment of asthma as prophylactic therapy in adults and children (5 years of age and above). It is also indicated for asthma patients who require systemic corticosteroid administration, where adding Bedometasone Dipropionate may reduce or eliminate the need for the systemic corticosteroids.

Bedometasone Dipropionate is not indicated for the relief of acute bronchospasm.

Dosage & administration:**Management of chronic asthma**

Adults & children over 12 years: 100-400 µg twice daily, Maximum 1000 µg twice daily.

Children (5-12 years): 100-200 µg twice daily, Maximum 200-400 µg twice daily.

Prophylaxis of asthma

Adults & children over 12 years: 50-200 µg twice daily. Increased if necessary to maximum 400 µg twice daily.

Children (5-12 years): The usual starting dose is 100 µg twice daily. Depending on the severity of asthma, the daily dose may be increased up to 400 µg administered in 2-4 divided doses.

When patient's symptoms remain under satisfactory control, the dose should be titrated to the lowest dose at which effective control of asthma is maintained.

Therapy in new patients:

Mild asthma: 50-100 µg twice daily.

Moderate asthma: 100-200 µg twice daily.

Severe asthma: 200-400 µg twice daily.

When switching a patient with well-controlled asthma from another corticosteroid inhaler, initially a 100 µg puff of **Beclocort®-100 HFA** should be prescribed for-

- 200-250 µg of Bedometasone Dipropionate (CFC) or Budesonide.
- 100 µg of Fluticasone Propionate

When switching a patient with poorly controlled asthma from another corticosteroid inhaler, initially a 100 µg puff of **Beclocort®-100 HFA** should be prescribed for 100 µg of Bedometasone Dipropionate (CFC) or Budesonide or Fluticasone Propionate. The dose of **Beclocort® HFA** inhaler should be adjusted according to response.

Contraindications:

Beclocort® HFA inhaler is contraindicated in patients with hypersensitivity to Bedometasone Dipropionate or any other ingredient of Bedometasone this preparation.

Side effects:

Beclocort® HFA inhaler has been found generally well tolerated. The adverse effects that occurred in a very few patients are headache, pharyngitis, upper respiratory tract infection, rhinitis, sinusitis, pain, back pain, nausea, dysphonia etc. When taking Bedometasone Dipropionate, an occasional incidence of hoarseness and/or a rare occurrence of candidiasis of throat and mouth may occur; patients may find it helpful

to rinse out their mouth with water after using their inhaler to reduce the risk of candidiasis and hoarseness. Topical anti-fungal therapy can be used for the treatment of candidiasis while continuing treatment with Bedometasone Dipropionate. Special care is necessary in patients with active or quiescent pulmonary tuberculosis.

As with other inhaled therapy, paradoxical bronchospasm with wheezing may occur immediately after dosing. If it occurs, the preparation should be discontinued immediately and alternate therapy instituted. Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These may include adrenal suppression, growth retardation, decrease in bone mineral density in children and adolescents etc.

Precautions:

Patients should be instructed to use inhaler properly to ensure that the drug reaches the target areas within the lungs. They should also be made aware of the prophylactic nature of therapy with Bedometasone Dipropionate HFA inhaler and that they should use it regularly, even when they are asymptomatic. Bedometasone dipropionate is not suitable for the treatment of an acute asthma attack.

Replacement of systemic steroid treatment with inhaled therapy sometimes unmasks allergies such as allergic rhinitis or eczema previously controlled by the systemic drug.

Use in special groups:**Use in Pregnancy:**

There are no adequate and well-controlled studies in pregnant women. Bedometasone Dipropionate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in lactation:

It is reasonable to assume that Bedometasone Dipropionate is secreted in milk, but at the dosage used for direct inhalation there is low potential for significant level in breast milk.

The use of Bedometasone Dipropionate in breast-feeding mothers requires that the therapeutic benefits of the drug should be outweighed against the potential hazards to the mother and baby.

Use in elderly or patients with hepatic or renal impairment:

There are no special dosage recommendations for use in the elderly or in patients with hepatic or renal impairment.

Drug interactions:

Due to the very low plasma concentration achieved after inhaled dosing, clinically significant drug interactions are in general unlikely. Care should be taken when co-administering with known strong CYP 3A4 inhibitors (e.g. ketoconazole, itraconazole, nefinavir, ritonavir) as there is a potential for increased systemic exposure to Bedometasone.

Storage:

Pressurized canister. Do not puncture, break or burn even when apparently empty. Keep away from sunlight and heat. Store below 30°C. Do not freeze. Keep away from eyes. Keep away from children. To be dispensed only on or by the prescription of a registered physician.

Packing:

Beclocort®-50 HFA inhaler: Each canister contains 100 / 200 puffs.

Beclocort®-100 HFA inhaler: Each canister contains 100 / 200 puffs.

Beclocort®-250 HFA inhaler: Each canister contains 50 / 100 / 200 puffs.

HFA Inhaler

Beclocort®
Bedometasone Dipropionate



Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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