Bevicort™

Formoterol Fumarate 5.5 mcg, Glycopyrronium Bromide 10.4 mcg & Budesonide 182 mcg

Composition:
Bevicort™ HFA Inhaler: Each puff contains Formoterol Fumarate 5.5 mcg as Formoterol Fumarate Dihydrate Ph. Eur., Glycopyrronium Bromide Ph. Eur. 10.4 mcg and Budesonide Ph. Eur. 182 mcg.

Description:
Bevicort™ HFA Inhaler is a pressurized metered-dose inhaler that delivers a combination of micronized Budesonide, an inhaled corticosteroid (ICS), micronized Glycopyrronium Bromide (an anticholinergic), and micronized Formoterol Fumarate, an inhaled long-acting β2-adrenergic agonist (a LABA), for oral inhalation. ICS medicines such as Budesonide help to decrease inflammation in the lungs. Inflammation in the lungs can lead to breathing problems.
Anticholinergic medicines, such as Glycopyrronium Bromide, and LABA medicines, such as Formoterol Fumarate help the muscles around the airways in the lungs stay relaxed to prevent symptoms, such as wheezing, cough, chest tightness, and shortness of breath.

Indication:
Bevicort™ HFA Inhaler is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). It is not indicated for the relief of acute bronchospasm.

Dosage & Administration:
The recommended dosage of **Bevicort**™ HFA Inhaler is two inhalations twice daily in the morning and in the evening by oral inhalations. Do not take more than two inhalations twice daily. After inhalation, rinse mouth with water.

Contraindication:
It is contraindicated in patients who have demonstrated hypersensitivity to Budesonide, Glycopyrronium, Formoterol Fumarate or any of the excipients.

Adverse Reactions:
Most common adverse reactions are upper respiratory tract infection, pneumonia, back pain, oral candidiasis, influenza, muscle spasm, urinary tract infection, cough, sinusitis and diarrhea.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

Precaution:
- Should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm.
- The daily dosage should not be increased beyond the recommended dose.
- Patients should not use another medicine containing a LABA (e.g., salmeterol, Formoterol fumarate, arformoterol tartrate, indacaterol) for any reason.
- Caution should be exercised when considering the co-administration with long-term ketoconazole, and other known strong CYP3A4 inhibitors (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, telithromycin).
- Since patients with COPD often have multiple risk factors for reduced BMD, assessment of BMD is recommended prior to initiating this product and periodically thereafter.

Warning:
Pressurized canister, do not puncture, break or incinerate even when empty as canister may explode. Avoid exposure to direct sunlight or heat. Clean your inhaler regularly as per direction. For best results, the canister should be at room temperature before use. Shake well before each use.

Use in pregnancy & Lactation:
Pregnancy: There are no adequate and well-controlled studies with this product or with two of its individual components, Glycopyrronium or Formoterol Fumarate, in pregnant women to inform a drug-associated risk.
Lactation: There are no adequate and well-controlled studies on breastfed child or on milk production with this product or with two of its individual components, Glycopyrronium or Formoterol Fumarate.

Storage:
Store below 30°C. Keep in a dry place & protect from light. Keep out of the reach of children. Keep away from contact of eyes.

How Supplied:
Bevicort™ HFA Inhaler: Each canister contains 120 metered doses, each puff contains Formoterol Fumarate 5.5 mcg, Glycopyrronium Bromide 10.4 mcg and Budesonide 182 mcg.