Composition:
Budison F®-80 HFA inhaler: Each puff delivers Budesonide BP 80 mcg & Formoterol Fumarate Dihydrate BP 4.5 mcg.
Budison F®-160 HFA inhaler: Each puff delivers Budesonide BP 160 mcg & Formoterol Fumarate Dihydrate BP 4.5 mcg.

Pharmacology:
Budison F® HFA inhaler is a combination of Budesonide & Formoterol Fumarate Dihydrate. Budesonide is a corticosteroid that exhibits potent glucocorticoid activity.
Formoterol Fumarate Dihydrate is a long-acting selective $ß_2$-adrenergic agonist ($ß_2$-agonist) with a rapid onset of action.

Indications:
Budison F® HFA inhaler is indicated in the regular treatment of asthma, where use of a combination therapy (inhaled corticosteroid and long acting $ß_2$-agonist) is appropriate. It can be used as 1. both maintenance & reliever therapy of asthma or as 2. only maintenance therapy of asthma. If used as both maintenance & reliever therapy, the patient should keep the inhaler with him for rescue therapy all the time & take additional puffs during sudden attack. If it is used as only maintenance therapy patient should keep separate rapid-acting bronchodilator with him for rescue at all times.
It is also indicated in the maintenance treatment of airflow obstruction in patients with COPD including bronchitis & emphysema.

Dosage & administration:
For asthma:
As both maintenance and reliever therapy:
Adults and adolescents (12 years and older): The recommended maintenance dose is 1 puff twice daily or 2 puffs once daily. For some patients a maintenance dose of 2 puffs twice daily may be appropriate (for 160/4.5 mcg/inhalation only). Patients should take 1 additional puff as needed in response to symptoms. If symptoms persist after a few minutes, the additional puff should be taken. Not more than 6 puffs should be taken on any single occasion.
Children (4 years and older): The usual maintenance dose is 1-2 puffs once or twice daily. Patients should take 1 additional puff as needed in response to symptoms. If symptoms persist after a few minutes, the additional puff should be taken. Not more than 4 puffs should be taken on any single occasion.
A reassessment of asthma therapy should be considered in patients using an increasing number of **Budison F®** inhalations for symptom relief without achieving improved asthma control within 2 weeks. A total daily dose of more than 8 inhalations for adults and adolescents and 4 inhalations for children is not normally needed, however a total daily dose of up to 12 puffs for adults and adolescents and 8 inhalations for children could be used temporarily.
Only as maintenance therapy:
Adults (18 years and older): (80/4.5 and 160/4.5 mcg/inhalation): Usual dose is 1-2 puffs twice daily. Maximum dose is 4 puffs twice daily.
Adolescents (12-17 years): (80/4.5 and 160/4.5 mcg/inhalation): 1-2 puffs twice daily.
Children (4-11 years): 80/4.5 mcg/inhalation: 1-2 puffs once or twice daily.
For COPD:
The recommended dose is 2 puffs twice daily of Budison F 160 (160/4.5).

Contraindications:
Hypersensitivity to Budesonide, Formoterol or inhaled lactose.

Side effects:
Most commonly reported side effects are nasopharyngitis, headache, upper respiratory tract infection, pharyngolaryngeal pain, bronchitis, sinusitis, back pain, stomach discomfort, vomiting and oral candidiasis.

Precautions:
Do not use in combination of additional long-acting $ß_2$-agonist. Use with caution in patients with immunosuppressive disease like existing tuberculosis, fungal, viral, bacterial or parasitic infection or ocular herpes simplex. More serious or even fatal course of chickenpox or measles can occur in susceptible patients. Caution should be taken when transferring from oral steroids to **Budison F®**. In that case taper the systemic corticosteroids when transfering to **Budison F®**. Glaucoma, increased ocular pressure (IOP) and cataract have been reported in patients with asthma or COPD following the long-term administration of inhaled corticosteroids. Therefore, close monitoring is warranted in patients with a change in vision or with a history of IOP, glaucoma and/or cataract. Use with caution in patients with cardiovascular or CNS disorders, convulsive disorder, thyrotoxicosis, diabetes mellitus, and ketoacidosis. Concomitant use of Budesonide-Formoterol & nonpotassium-sparing diuretics may worsen electrocardiographic changes and/or hypokalemia associated with those diuretics. Caution should be taken while taking Budesonide-Formoterol with these preparations.

Use in special groups:
Use in pregnancy:
There are no adequate and well-controlled studies of Budesonide & Formoterol in pregnant women. This preparation should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Use in lactation:
Since there are no data from controlled trials on the use of Budesonide & Formoterol by nursing mothers, a decision should be made whether to discontinue breast feeding or to continue this preparation, taking into account the importance of this preparation to the mother.
Use in elderly patients:
Based on available data for Budesonide & Formoterol, no adjustment of dosage is needed in geriatric patients.
Use in children:
Safety & effectiveness of Budesonide & Formoterol in asthma patients below 4 years of age have not been established.
Drug Interactions:
Strong cytochrome P450 inhibitors like ritanovir, clarithromycin, telithromycin, itraconazole, nelfinavir, indinavir, ketoconazole etc. may cause increased systemic corticosteroid effects. Monoamino Oxidase Inhibitors and tricyclic antidepressants may potentiate effect of Formoterol on vascular system. ß-blockers may block bronchodilatory effects of ß-agonists and produces severe bronchospasm.

Storage:
Pressurized canister. Do not puncture, break or burn even when apparently empty. Keep away from sunlight and heat. Store below 25^0C, but don't keep in deep freeze. Can be used up to 3 months at room temperature after starting the first dose. Store the Inhaler with the mouthpiece down. Keep away from eyes. Keep away from children. To be dispensed only on or by the prescription of a registered physician.
Packing:
Budison F®-80 HFA inhaler: Each canister contains 60 / 120 / 200 puffs.
Budison F®-160 HFA inhaler: Each canister contains 60 / 120 / 200 puffs.

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HFA Inhaler

Budison F®

Budesonide & Formoterol Fumarate Dihydrate

CFC Free

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