

Budison F[®] Arocap

Budesonide & Formoterol Fumarate Dihydrate
Dry Powder Inhalation Capsule

COMPOSITION

Budison F[®]-100 Arocap: Each inhalation capsule contains Budesonide BP 100 µg and Formoterol Fumarate Dihydrate BP 6 µg.

Budison F[®]-200 Arocap: Each inhalation capsule contains Budesonide BP 200 µg and Formoterol Fumarate Dihydrate BP 6 µg.

Budison F[®]-400 Arocap: Each inhalation capsule contains Budesonide BP 400 µg and Formoterol Fumarate Dihydrate BP 12 µg.

PHARMACOLOGY

Budison F[®] Arocap is a combination of Budesonide & Formoterol Fumarate Dihydrate. Budesonide is an anti-inflammatory corticosteroid that exhibits potent glucocorticoid activity. Formoterol Fumarate Dihydrate is a long-acting selective β_2 -adrenergic agonist (β_2 -agonist) with a rapid onset of action.

INDICATIONS

Budison F[®] Arocap is indicated in the regular treatment of asthma, where use of a combination therapy (inhaled corticosteroid and long acting β_2 -agonist) is appropriate. It is also indicated in the maintenance treatment of patients with Chronic Obstructive Pulmonary Disease (COPD).

DOSAGE AND ADMINISTRATION

Asthma

Dosage is individual and should be adjusted according to disease severity. When a control has been achieved, the dose should be titrated to the lowest effective dose.

For Budison F Arocap there are two treatment approaches:

(1) As Maintenance Therapy: Patients should always be advised to have their separate rapid acting bronchodilator available for rescue use.

Adults (18 Years and Older)-

Budison F[®]-100 and 200 Arocap: 1-2 Arocaps, twice daily, maximum dose is 4 Arocaps, twice daily.

Budison F[®]-400 Arocap: 1 Arocap, twice daily, maximum dose is 2 Arocaps, twice daily.

Adolescents (12-17 Years)-

Budison F[®]-100 Arocap: 1-2 Arocaps, twice daily.

Budison F[®]-200 Arocap: 1-2 Arocaps, twice daily.

Budison F[®]-400 Arocap: 1 Arocap, twice daily.

Children (6-11 Years)-

Budison F[®]-100 Arocap: 2 Arocaps, twice daily.

(2) Single Maintenance and Reliever Therapy: (For **Budison F[®]-100** and **200** Arocap only) Patients should take a daily maintenance dose of **Budison F[®]** and in addition take **Budison F[®]** as needed in response to symptoms. Patients should be advised to always have **Budison F[®]** available for use.

Adults (18 years and older)-

The recommended dose is 2 Arocaps per day as maintenance therapy (either one Arocap twice daily, or two Arocaps in either the morning or the evening), although some patients may require two Arocaps twice daily. Patients should take 1 additional Arocap as needed in response to symptoms. If symptoms persist after a few minutes, an additional Arocap should be taken. Not more than 6 Arocaps should be taken on any single occasion. A total daily dose of more than 8 Arocaps is not normally needed; however, a total daily dose of up to 12 Arocaps could be used for a limited period. Patients using more than 8 Arocaps daily should be strongly recommended to seek medical advice.

COPD (Chronic Obstructive Pulmonary Disease)

Budison F[®]-200 Arocap: 2 Arocaps, twice daily.

Insert the Arocap in the AroHaler immediately before use.

Using the AroHaler: This is a patient friendly, ready to use and easy to grip device. Use as per instruction for use.

CONTRAINDICATIONS

Budison F[®] Arocap is contraindicated in patients with hypersensitivity to any of the active substances or to the excipients of this preparation.

SIDE EFFECTS

Since **Budison F[®]** Arocap contains both Budesonide and Formoterol, the same pattern of undesirable effects as reported for these substances may occur. No increased incidence of adverse reactions has been seen following concurrent administration of the two compounds.

Formoterol: Most common adverse events with Formoterol are tremor, palpitations, headache etc. some uncommon and rare adverse events that occurred in the groups receiving Formoterol are cardiac arrhythmias, muscle cramps, and hypersensitivity reactions such as rash, oedema and angio-oedema etc.

Budesonide: The incidence of common adverse events with Budesonide are oropharyngeal candidiasis, hoarseness or throat irritation, dysphonia, back pain, nausea, sinusitis, adrenal suppression, etc.

WARNINGS AND PRECAUTIONS

It is recommended that the dose is tapered when the treatment is discontinued and should not be stopped abruptly. If patients find the treatment ineffective or exceed the highest recommended dose of **Budison F[®]** Arocap, medical attention must be sought.

Sudden and progressive deterioration in control of asthma is potentially life threatening and the patient should undergo urgent medical assessment. In this situation patients should be advised to always have their rescue inhaler available, either **Budison F[®]** Arocap (for patients using **Budison F[®]** Arocap as maintenance and reliever therapy) or a separate rapid-acting bronchodilator (for patients using **Budison F[®]** Arocap as maintenance therapy only). Patients should be reminded to take their **Budison F[®]** Arocap maintenance dose as prescribed, even when asymptomatic. Once asthma symptoms are controlled, consideration may be given to gradually reducing the dose of **Budison F[®]** Arocap. Regular review of patients as treatment is stepped down is important. The lowest effective dose of **Budison F[®]** Arocap should be used.

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, considering the importance of this preparation to the mother.

Use in elderly patients: There are no special dosing requirements for elderly patients.

Use in children: Safety & effectiveness of Budesonide & Formoterol in asthma patients below 6 years of age have not been established.

DRUG INTERACTIONS

Strong cytochrome P450 inhibitors like ritonavir, clarithromycin, telithromycin, itraconazole, neflavinir, indinavir, ketoconazole etc. may cause increased systemic corticosteroid effects. Monoamino Oxidase Inhibitors and tricyclic antidepressants may potentiate effect of Formoterol on vascular system. β -blockers may block bronchodilatory effects of β -agonists and produces severe bronchospasm.

STORAGE

Store below 30°C, keep in dry place & protect from light. Keep out of the reach of children.

PACKING

Budison F[®]-100 Arocap: Each box contains 30's capsules in alu-alu blister pack.

Budison F[®]-200 Arocap: Each box contains 30's capsules in alu-alu blister pack.

Budison F[®]-400 Arocap: Each box contains 30's capsules in alu-alu blister pack.

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

20005828/00