

Composition : Budetrol 6/100 Mycap: Each Capsule Contains Formoterol Fumarate Dihydrate BP 6 mcg and Budesonide BP 100 mcg inhalation powder.

Budetrol 6/200 Mycap : Each Capsule Contains Formoterol Fumarate Dihydrate BP 6 mcg and Budesonide BP 200 mcg inhalation powder.

Budetrol 12/400 Mycap : Each Capsule Contains Formoterol Fumarate Dihydrate BP 12 mcg and Budesonide BP 400 mcg inhalation powder.

Description : Budesonide is a glucocorticosteroid which when inhaled has a rapid (within hours) and dose dependent anti-inflammatory action in the airways, resulting in reduced symptoms and fewer asthma exacerbations. Formoterol Fumarate Dihydrate is a long acting B₂-adrenoreceptor agonist having rapid onset of action.

Indications : Asthma : Formoterol and Budesonide combination is indicated in the regular treatment of asthma where use of a combination (inhaled corticosteroid and long acting β 2-agonist) is appropriate. This includes :

*patients who are not adequately controlled with inhaled corticosteroid therapy and as needed inhaled short-acting β 2-adrenoceptor agonists.

*patients who are already adequately controlled on regular separate long-acting β 2-agonist and inhaled corticosteroid therapies.

COPD : Formoterol and Budesonide combination is indicated in the regular treatment of adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) with frequent symptoms despite β 2-agonist use and a history of exacerbations.

Dosage and administration : Asthma : Dpsage is individual and should be adjusted according to disease severity. When control has been achieved, the dose should be titrated to the lowest effective dose. For Budetrol Mycap there are two treatment approaches: **1. Maintenance Therapy : Budetrol Mycap** is taken as regular maintenance treatment with a separate rapid acting bronchodilator as rescue. **2. Single Maintenance And Reliever Therapy : Budetrol Mycap** is taken as regular maintenance and as needed in response to symptoms. **1. Maintenance Therapy :** Patients should be advised to have their separate rapid acting bronchodilator available for rescue use at all times.

Adults (18 Years and Older) : Budetrol 6/100 Mycap : 1-2 Mycap capsules, twice daily. Maximum dose is 4 Mycap capsules, twice daily. **Budetrol 6/200 Mycap :** 1-2 Mycap capsules, twice daily. Maximum dose is 4 Mycap capsules, twice daily. **Budetrol 12/400 Mycap :** 1 Mycap capsule, twice daily. Maximum dose is 2 Mycap capsules, twice daily. **Adolescents (12-17 Years) : Budetrol 6/100 Mycap :** 1-2 Mycap capsules, twice daily. **Budetrol 6/200 Mycap :** 1-2 Mycap capsules, twice daily. **Budetrol 12/400 Mycap :** 1 Mycap capsule, twice daily. **Children (6-11 Years): Budetrol 6/100 Mycap :** 2 Mycap capsules, twice daily. **2. Single Maintenance And Reliever Therapy (For Budetrol 6/100 and Budetrol 6/200) :** Patients take a daily maintenance dose of **Budetrol Mycap** and in combination take **Budetrol Mycap** as needed in response to symptoms. Patients should be advised to always have **Budetrol Mycap** available for use. **Adults (12 years and older) :** The recommended maintenance dose is 2 **Budetrol Mycap** per day, given either as one inhalation in the morning and evening or as 2 **Budetrol Mycap** in either the morning or evening. For some patients a maintenance dose of 2 **Budetrol Mycap** twice daily may be appropriate.

Budetrol Mycap Capsule



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Patients should take 1 additional **Budetrol Mycap** as needed in response to symptoms. If symptoms persist after a few minutes, an additional **Budetrol Mycap** should be taken. Not more than 6 **Budetrol Mycap** should be taken on any single occasion. A total daily dose of more than 8 Budetrol Mycap is not normally needed; however, a total daily dose of up to 12 **Budetrol Mycap** could be used for a limited period. Patients using more than 8 **Budetrol Mycap** daily should be strongly recommended to seek medical advice.

COPD (Chronic Obstructive Pulmonary Disease) : Budetrol 6/200 Mycap : 2 Mycap capsules, twice daily. **Budetrol 12/400 Mycap :** 1 Mycap capsule, twice daily. Or, as directed by the registered physician. Rinsing the mouth after each inhalation is advised.

Contraindication : It is contraindicated in patients with a hypersensitivity to Budesonide and Formoterol Fumarate Dihydrate or any other components of this product.

Precautions : Treatment with Formoterol and Budesonide combination should not be initiated to treat a severe exacerbation or if patients have significantly worsening or acutely deteriorating asthma.

Side effects : The most common drug related adverse reactions are pharmacologically predictable side effects of β 2-agonist therapy, such as tremor and palpitations. Adverse events which have been associated with Formoterol and Budesonide are palpitations, candida infections in oropharynx, headache, tremor, coughing, hoarseness and tachycardia etc.

Use in Pregnancy and Lactation : Pregnancy category C. There are no adequate and well controlled studies in pregnant woman. It should be used during pregnancy only if the potential benefit justifies the potential risk of fetus. Budesonide is excreted in human milk. It is not known whether Formoterol is excreted in human milk. Caution should be exercised when Formoterol is administered to a nursing woman.

Use In Child : The safety & Effectiveness of this medicine In Children with Asthma less than 4 years of age have not been established. Patient's using less than 4 years of age Should be strongly recommended to seek medical advice.

Drug Interactions : It should be used with caution when it is administered concomitant with Ritonavir, Itraconazole, Ketoconazole or other potent CYP3A4 inhibitors .

Overdose : An overdose of formoterol would likely lead to effects that are typical for β 2-adrenoceptor agonists : tremor, headache, palpitations. Acute overdose with budesonide, over in excessive doses, is not expected to be a clinical problem. When used chronically in excessive doses, systemic glucocorticosteroid effects, such as hypercorticism and adrenal suppression, may appear.

Storage : Store below 30° C in a dry place. Protect from light & freezing. Insert the Mycap in the Myhaler just prior to use to protect from deterioration by moisture.

Packing : Budetrol 6/100 Mycap : Each box contains 3x10's capsules in Alu-Alu blister pack.

Budetrol 6/200 Mycap : Each box contains 3x10's capsules in Alu-Alu blister pack.

Budetrol 12/400 Mycap : Each box contains 3x10's capsules in Alu-Alu blister pack.