Symbion® Bexi cap

Dry Powder Inhaler

Formoterol Fumarate Dihydrate and Budesonide Capsule

Description

Formoterol is a very potent, long-acting, beta2 adrenoceptor-agonist with a high intrinsic activity and a rapid onset of action. Symbion® Bexicap capsule is a combination of Formoterol Fumarate Dihydrate and Budesonide. Budesonide is a potent glucocorticoid that binds with high affinity to the glucocorticoid receptor. It has a high ratio of topical to systemic activity.

Indications

Symbion® Bexicap is indicated in the regular treatment of asthma, where the use of a combination (long-acting, beta2-agonist and inhaled corticosteroid) has been found to be appropriate. It is also indicated in the symptomatic treatment of severe chronic obstructive pulmonary disease (COPD), with a history of repeated exacerbations despite regular therapy with long-acting bronchodilators.

Dosage and Administration

Asthma

Dosage 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 Symbion® Bexicap, there are two treatment approaches:

A. Maintenance Therapy: Symbion® Bexicap is taken as regular maintenance treatment with a separate rapid acting bronchodilator as rescue.

B. Single maintenance and reliever therapy: Symbion® Bexicap is taken as regular maintenance and as needed in response to symptoms.

A. 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)

Symbion® 6/100 Bexicap capsule: 1-2 Bexicap capsules, twice daily

Maximum dose is 4 Bexicap capsules, twice daily

Symbion® 6/200 Bexicap capsule: 1-2 Bexicap capsule, twice daily

Maximum dose is 4 Bexicap capsules twice daily

Adolescents (12-17 Years)

Symbion® 6/100 Bexicap capsule: 1-2 Bexicap capsules, twice daily

Symbion® 6/200 Bexicap: 1-2 Bexicap capsules, twice daily

Children (6-11 Years)

Symbion® 6/100 Bexicap: 2 Bexicap capsules, twice daily

B. Single Maintenance and Reliever Therapy (For Symbion 6/100 Bexicap and 6/200 only)

Patients take a daily maintenance dose of Symbion® Bexicap and in combination take Symbion® Bexicap as needed in response to symptoms. Patients should be advised to always have Symbion® Bexicap available for use.

Adults (18 years and older): The recommended maintenance dosage is 2 inhalations per day as maintenance therapy (either one inhalation twice daily, or two inhalations in either the morning or the evening), although some patients may require two inhalations twice daily.

Patients should take 1 additional inhalation as needed in response to symptoms. If symptoms persist after a few minutes, an additional inhalation should be taken.

Not more than 6 inhalations should be taken on any single occasion.

A total daily dose of more than 8 inhalations is not normally needed; however, a total daily dose of up of 12 inhalations could be used for a limited period. Patients using more than 8 inhalations daily should be strongly recommended to seek medical advice.

COPD (Chronic Obstructive Pulmonary Disease)

Symbion® 6/200 Bexicap: 2 Bexicap capsule, twice daily

Contraindications

Symbion® Bexicap is contraindicated in patients with a history of hypersensitivity to any of the components of the drug product.

Pharmacodynamics Properties

Mechnism of action

Symbion® Bexicap capsule contains both Budesonide and Formoterol; therefore, the mechanisms of action described below for the individual components apply to Symbion® Bexicap. These drugs represent two classes of medications (asynthetic corticosteroid and a long-acting, selective beta2-adrenoceptor agonist) that have

different effects on the clinical, physiological, and inflammatory indices of Chronic Obstructive Pulmonary Disease (COPD) and asthma.

Budesonide: Budesonide is an anti-inflammatory corticosteroid that exhibits potent glucocorticoid activity and weak mineralocorticoid activity. Corticosteroids have a wide range of inhibitory activities against multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in allergic and non-allergic-mediated inflammation. These anti-inflammatory actions of corticosteroids may contribute to their efficacy in COPD and asthma

Formoterol Fumarate: Formoterol Fumarate is a long-acting, selective beta2-adrenergic agonist with a rapid onset of action. Inhaled Formoterol Fumarate acts locally in the lungs as a bronchodilator.

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 Symbion® Bexicap, 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 consideration should be given to the need for increased therapy with corticosteroids e.g. a course of oral corticosteroids, or antibiotic treatment if an infection is present. Patients should be advised to have their rescue inhaler available at all times, either Symbion® Bexicap (for patients using Symbion® Bexicap as maintenance and reliever therapy) or a separate rapid-acting bronchodilator (for patients using Symbion® Bexicap as maintenance therapy only). Patients should be reminded to take their Symbion® Bexicap maintenance dose as prescribed, even when asymptomatic. The prophylactic use of Symbion® Bexicap, e.g. before exercise, has not been studied. Once asthma symptoms are controlled, consideration may be given to gradually reducing the dose of Symbion® Bexicap. Regular review of patients as treatment is stepped down is important. The lowest effective dose of Symbion® Bexicap should be used.

Precaution for Paediatric use

It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroids is regularly monitored. If growth is slowed, therapy should be re-evaluated with the aim of reducing the dose of inhaled corticosteroid. The benefits of the corticosteroid therapy and the possible risks of growth suppression must be carefully weighed. In addition consideration should be given to referring the patient to a paediatric respiratory specialist. Limited data from long-term studies suggest that most children and adolescents treated with inhaled budesonide will ultimately achieve their adult target height.

Drug Interactions

The metabolic conversion of Budesonide is impeded by substances metabolized by CYP P450 3A4 (e.g. itraconazole, ritonavir). The concomitant administration of these potent inhibitors of CYP P450 3A4 may increase plasma levels of Budesonide. The concomitant use of these drugs should be avoided unless the benefit outweighs the increased risk of systemic side-effects. In patients using potent CYP3A4 inhibitors, Symbion® Bexicap maintenance and reliever therapy is not recommended.

Use During Pregnancy and Lactation

There are no adequate data from use of Formoterol and Budesonide in pregnant women. Administration of Symbion® Bexicap in pregnant women should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

Budesonide is excreted in breast milk. However, at therapeutic doses no effects on the suckling child are anticipated. It is not known whether Formoterol passes into human breast milk.

Side Effects

Since Symbion® Bexicap 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.

Pharmaceutical Precautions

Bexicap must not be swallowed. Only to be used with Bexihaler. Avoid storage in direct sunlight or heat. Store below 30°C. Keep away from children.

Remove Bexicap capsule from the blister pack only immediately before use it in the Bexihaler as Bexicap capsule exposed to moisture may not be pierced easily.

Commercial Pack

Symbion® 6/100 Bexicap capsule: Box containing 30 capsules in alu-alu blister strips. Each Bexicap capsule contains Formoterol Fumarate Dihydrate BP 6 µg and Budesonide BP 100 µg.

Symbion® 6/200 Bexicap Capsule: Box containing 30 capsules in alu-alu blister strips. Each Bexicap capsule contains Formoterol Fumarate Dihydrate BP 6 µg & Budesonide BP 200 µg.

Manufactured by

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