For the use of a registered medical practitioner or a hospital or a laboratory only

Symbicort Turbuhaler® (Budesonide/Formoterol Inhalation Powder 160/4.5µg/dose)

Abbreviated prescribing information

COMPOSITION:

Each delivered dose contains: Budesonide IP 160 mcg, Formoterol fumarate dihydrate IP: 4.5 mcg, Lactose monohydrate Ph.Eur. 730 mcg

THERAPEUTIC INDICATIONS:

Asthma: Symbicort Turbuhaler is indicated in the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting beta2-agonist) is appropriate: patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short-acting beta2-agonists or patients already adequately controlled on both inhaled corticosteroids and long acting beta2-agonists.

COPD: Symbicort Turbuhaler is indicated in the regular treatment of patients with moderate to severe Chronic Obstructive Pulmonary Diseases (COPD), with frequent symptoms and a history of exacerbations.

For Symbicort there are two treatment approaches:

A. Symbicort 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): 1-2 inhalations twice daily. Some patients may require up to a maximum of 4 inhalations twice daily; Adolescents (12-17 years): 1-2 inhalations twice daily; Children (4 years and older): 1 inhalation twice daily. Maximum daily dose: 2 inhalations.

B. Symbicort maintenance and reliever therapy: Patients take a daily maintenance dose of Symbicort and in addition take Symbicort as needed in response to symptoms. Patients should be advised to always have Symbicort available for rescue use. Recommended doses: Adults and adolescents (12 years & older): The recommended maintenance dose is 2 inhalations/ day, given either as one inhalation in the morning and evening or as 2 inhalations in either the morning or the evening. For some patients, a maintenance dose of 2 inhalations twice daily may be appropriate. 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 normally not needed, however a total daily dose of up to 12 inhalations can be used temporarily. If the patient experiences deteriorating symptoms after taking the appropriate maintenance therapy and additional as-needed inhalations, the patient should be reassessed for alternative explanations of persisting symptoms.

Children under 12 years: Symbicort maintenance and reliever therapy is not recommended for children.

COPD: Recommended doses: Adults (18 Years and Older): 2 inhalations twice daily. Maximum daily dose: 4 inhalations

CONTRAINDICATIONS:

Hypersensitivity (allergy) to Budesonide, formoterol or inhaled lactose. Special warning and precautions for use: Patients should be reminded to take their Symbicort maintenance dose as prescribed, even when asymptomatic. The prophylactic use of Symbicort, e.g. before exercise, has not been studied. Potential effects on bone density should be considered particularly in patients on high doses for prolonged periods that have coexisting risk factors for osteoporosis. No information regarding the effect of Symbicort at higher doses is available.

Symbicort should be administered with caution in patients with thyrotoxicosis, phaeochromocytoma, diabetes mellitus, untreated hypokalaemia, hypertrophic obstructive cardiomyopathy, idiopathic subvalvular aortic stenosis, severe hypertension, aneurysm or other severe cardiovascular disorders, such as ischaemic heart disease, tachyarrhythmias or severe heart failure. Concomitant treatment with xanthine-derivatives, steroids and diuretics may result in potentially serious hypokalaemia.

PREGNANCY AND LACTATION:

For Symbicort, no clinical data on exposed pregnancies are available. During pregnancy, Symbicort should only be used when the benefits outweigh the potential risks. The lowest effective dose of Budesonide needed to maintain adequate asthma control should be used. It is not known whether Formoterol or Budesonide passes into human breast milk.

INTERACTIONS:

Concomitant administration of itraconazole and ritonavir may increase plasma levels of Budesonide. Beta-adrenergic blockers can weaken or inhibit the effect of Formoterol. Symbicort should therefore not be given together with beta-adrenergic blockers.

UNDESIRABLE EFFECTS:

No increased incidence of adverse reactions has been seen following concurrent administration of the two compounds. The most common drug-related adverse reactions are pharmacologically predictable side effects of beta2-agonist therapy, such as tremor and palpitations. These tend to be mild and usually disappear within a few days of treatment.

Common: Palpitations, candida infections in the oropharynx, headache, tremor, mild irritation in the throat, coughing and hoarseness

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Uncommon: Tachycardia, nausea, muscle cramps, dizziness, agitation, restlessness, nervousness, sleep disturbances and bruises. Presentation: Inhaler with Budesonide 160 mcg & Formoterol 4.5 mcg, 60 metered doses.

Symbicort ™ is an applied trademark of AstraZeneca group of companies.

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For more information, refer full prescribing information version 3 dated 24th May 2016.