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

Symbicort Turbuhaler® (Budesonide/Formoterol Inhalation Powder 80/4.5µg/dose)

Abbreviated prescribing information

COMPOSITION:

Each delivered dose contains: Budesonide IP 80 mcg, Formoterol fumarate dihydrate IP: 4.5 mcg, Lactose monohydrate Ph.Eur. 810 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.

POSOLOGY AND ADMINISTRATION:

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. Recommended doses: Adults (18 years and older): 1-2 inhalations once or twice daily. Some patients may require up to a maximum of 4 inhalations twice daily; Adolescents (12-17 years): 1-2 inhalations once or twice daily; Children (4 years and older): 1 inhalation twice daily. Maximum daily dose: 4 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 of asthma. 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. 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 for asthma is not recommended for children.

CONTRAINDICATIONS:

Hypersensitivity (allergy) to Budesonide, formoterol or inhaled lactose.

SPECIAL WARNING AND PRECAUTIONS FOR USE:

It is recommended that the dose is tapered when long-term treatment is discontinued and should not be stopped abruptly.

Physicians should closely follow the growth of children and adolescents taking long-term corticosteroids by any route, and weigh the benefits of the corticosteroid therapy against the possible risk of growth suppression. Particular care is needed in patients transferring from oral steroids, since they may remain at risk of impaired adrenal function for a considerable time. Patients who have required high dose emergency corticosteroid therapy may also be at risk. Additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.

Symbicort should be administered with caution in patients with severe cardiovascular disorders (including heart rhythm abnormalities), diabetes mellitus, untreated hypokalaemia or thyrotoxicosis.

PREGNANCY AND LACTATION:

For Symbicort, no clinical data on exposed pregnancies are available. During pregnancy, Symbicort Turbuhaler should only be used after special consideration, especially during the first three months and shortly before delivery. 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 ketoconazole 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.

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For more information, refer full prescribing information

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