

For the use of Registered Medical Practitioner or Hospital use or Laboratory use only

Symbicort® Turbuhaler®

Composition: Each delivered dose of **Symbicort** Turbuhaler contains: Budesonide 160 mcg and formoterol 4.5 mcg.

Description: Symbicort Turbuhaler contains budesonide and formoterol, which show additive effects in terms of reduction of asthma exacerbations. Budesonide is a glucocorticosteroid with high local anti-inflammatory effect. Improvement in asthma control can occur within 24 hours with maximum clinical benefit usually achieved within 1 to 2 weeks. Formoterol is a selective β 2-adrenergic agonist that produces relaxation of bronchial smooth muscle. The bronchodilating effect sets in rapidly, within 1–3 minutes after inhalation and has duration of 12 hours after a single dose.

Indications: Regular treatment of asthma where use of a combination (inhaled corticosteroid and long acting beta-agonist) is appropriate.

Warnings and Precautions: There are no data available on the use of Symbicort Turbuhaler in the treatment of an acute asthma attack. Particular care is needed for patients who have transferred from systemic to inhaled glucocorticosteroids. Excessive doses of, or long-term treatment with glucocorticosteroids may lead to signs or symptoms of hypercorticism, suppression of HPA function and/or suppression of growth in children and adolescents. The growth of children and adolescents taking glucocorticosteroids in long-term treatment by any route should be monitored. Symbicort Turbuhaler should be administered with caution in patients with severe cardiovascular disorders, diabetes mellitus, untreated hypokalemia or thyrotoxicosis. *Pregnancy and lactation:* As with other drugs administered during pregnancy, the benefits for the mother should be weighed against the risks for the fetus. It is not known whether budesonide or formoterol passes into human milk.

Adverse effects: *Common:* Headache, palpitations, tremor, candida infection in the oropharynx, mild throat irritation, coughing, and hoarseness. *Uncommon:* Tachycardia, muscle cramps, agitation, restlessness, nervousness, nausea, dizziness, sleep disturbances. *Rare:* Exanthema, urticaria, pruritus, skin bruising, and bronchospasm. *Other rare or very rare;* (budesonide) Psychiatric symptoms such as depression, behavioural disturbances, signs or symptoms of systemic glucocorticosteroid effects, immediate and delayed hypersensitivity reactions (including dermatitis and angioedema). (formoterol) angina pectoris, hyperglycaemia, cardiac arrhythmias.

Dosage and Administration: Dosage is individual according to disease severity. When control has been achieved, the dose should be titrated to the lowest dose at which effective control of symptoms is maintained. To minimise oropharyngeal thrush, rinse the mouth out with water after each dosing occasion. *Adults and adolescents (12 years and above):* In general, the recommended maintenance dose is 1–2 inhalations once or twice daily. *Children under 12 years:* Symbicort Turbuhaler has not yet been approved for use in children under 12 years.

Presentation: Symbicort® Turbuhaler® 160/4.5 mcg contains 60 metered doses.

For further information please contact:

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