Abbreviated Prescribing Information

SYMBICORT® TURBUHALER®

Composition:

Each delivered dose contains:
Budesonide IP 320 mcg,
Formoterol fumarate dihydrate IP: 9.0 mcg,
Lactose monohydrate Ph. Eur. 491 mcg.

Pharmaceutical Form

Budesonide/Formoterol Inhalation Powder SYMBICORT® TURBUHALER® 320/9.0µg/dose

Therapeutic Indications and Usage:

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.

Symbicort 320/9 micrograms/inhalation should be used as Symbicort maintenance therapy only. Symbicort maintenance therapy: Patients should be advised to have their separate rapid-acting bronchodilator available for rescue use at all times.

Recommended doses:

Asthma:

Adults (18 years and older): 1 inhalations once or twice daily. In some cases up to a maximum of 2 inhalations twice daily may be required as maintenance dose or temporarily during worsening of asthma.;

Adolescents (12-17 years): 1 inhalations once or twice daily; During worsening of asthma the dose may temporarily be increased to a maximum of 2 inhalations twice daily.;

Children (4 years and older): Efficacy and safety have not been studied in children for Symbicort 320/9 micrograms/inhalation.

COPD:

Adult (18 years and older): 1 inhalation twice daily. Maximum daily dose: 2 inhalations.

Contraindications: Hypersensitivity 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. Treatment with Symbicort Turbuhaler should not be initiated to treat a severe exacerbation. 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. Symbicort Turbuhaler should be administered with caution in patients with severe

cardiovascular disorders (including heart rhythm abnormalities), diabetes mellitus, untreated hypokalaemia or thyrotoxicosis. High doses of beta2-agonists can lower s-potassium by inducing a redistribution of potassium from the extracellular to the intracellular compartment, via stimulation of Na+/K+-ATPase in muscle cells. The clinical importance of this effect is uncertain.

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. 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. A Clinical Pharmacology Study has shown that inhaled budesonide is excreted in breast milk. However, budesonide was not detected in nursing infant blood samples. It is not known whether Formoterol passes into human breast milk. Administration of Symbicort to women who are breastfeeding should only be considered if the expected benefit to the mother is greater than any possible risk to the child. Interactions: Concomitant treatment with beta-adrenergic blockers (including eye drops) can weaken or inhibit the effect of formoterol. Symbicort should therefore not be given together with beta-adrenergic blockers. The metabolism of budesonide is primarily mediated by the enzyme CYP3A4. Inhibitors of this enzyme, eg, ketoconazole, may therefore increase systemic exposure to budesonide. Undesirable effects: No increased incidence of adverse reactions has been seen following concurrent administration of the two compounds.

ADVERSE REACTIONS:

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; Uncommon: Tachycardia, nausea, muscle cramps, dizziness, agitation, restlessness, nervousness, sleep disturbances and bruises. Presentation: Inhaler with Budesonide 320 mcg & Formoterol 9.0 mcg, 60 metered doses.

API based on PI Version 1 dated 13/04/2016.

Kindly refer full prescribing information before prescribing the product.