Starting SYMBICORT® TURBUHALER® Anti-Inflammatory Reliever Therapy

Patient Counselling Tear Pad

SYMBICORT TURBUHALER is indicated for the treatment of asthma in patients 12 years and older with reversible obstructive airways disease.

PrSymbicort®
budesonide/formoterol fumarate dihydrate

PHARMACODYNAMIC PROFILE

SYMBICORT TURBUHALER demonstrated rapid onset of effect[1*]

- SYMBICORT TURBUHALER and the short-acting bronchodilator salbutamol have been shown to have similarly rapid onsets of effect

MODE OF ACTION

SYMBICORT TURBUHALER contains 2 active molecules (budesonide and formoterol) in 1 inhaler[1*]

- Budesonide and formoterol fumarate dihydrate have different modes of action and show additive effects in terms of the reduction of asthma exacerbations
- SYMBICORT TURBUHALER can be used as anti-inflammatory reliever plus maintenance therapy due to the **rapid bronchodilator effect** of formoterol and the **anti-inflammatory effects** of budesonide

Important safety note: Patients should take no more than 6 inhalations on any single occasion and no more than 8 inhalations in a day when using SYMBICORT TURBUHALER as anti-inflammatory reliever plus maintenance therapy.

1 INHALER =
CONTROLLER medication
+ RELIEVER medication*

Reference: 1. Symbicort® Turbuhaler® Product Monograph. AstraZeneca Canada Inc. February 8, 2021.

* Clinical significance has not been established.

REVIEWED BY PAAB

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AstraZeneca

Clinical use:

SYMBICORT TURBUHALER can be used according to three different treatment approaches:

A. SYMBICORT TURBUHALER Anti-inflammatory Reliever Therapy: in patients with mild persistent asthma, SYMBICORT *200* TURBUHALER is taken as needed for relief of asthma symptoms when they occur.
SYMBICORT TURBUHALER has not been evaluated in patients whose asthma can be managed by occasional use of a rapid onset, short duration, inhaled beta$_2$-agonist.

B. SYMBICORT TURBUHALER Anti-inflammatory Reliever plus Maintenance Therapy: in patients with moderate or severe asthma, SYMBICORT *100* TURBUHALER or SYMBICORT *200* TURBUHALER are taken both as daily maintenance therapy and as needed for relief of asthma symptoms when they occur.

C. SYMBICORT TURBUHALER Maintenance Therapy: in patients with moderate or severe asthma, SYMBICORT TURBUHALER is taken as a fixed-dose daily treatment with a separate short-acting bronchodilator for relief of symptoms when they occur.

Once asthma control is achieved and maintained, the patient should be assessed at regular intervals.

Contraindications:

• Hypersensitivity to inhaled lactose.

Most serious warnings and precautions:

Risk of serious asthma-related events — hospitalizations, intubations, and death: Use of long-acting beta$_2$-agonists (LABA) as monotherapy (without inhaled corticosteroids [ICS]) will increase the risk of asthma-related death and the risk of asthma-related hospitalizations in pediatric and adolescent patients. These findings are considered a class effect of LABA monotherapy. When LABA are used in fixed-dose combination with ICS, data from large clinical trials do not show a significant increase in the risk of serious asthma-related events (hospitalizations, intubations, death) compared with ICS alone.

Asthma reliever medication: Inform patients to have reliever medication available at all times. Asthma patients should be clearly instructed to use medication for relief of asthma symptoms (e.g., SYMBICORT TURBUHALER, terbutaline, or salbutamol).

Excessive use and use with other LABA products: Do not exceed the prescribed SYMBICORT TURBUHALER dose. Cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs.

Use in adolescents: Periodic reassessment should be considered as severity of asthma may vary with age. Possible systemic effects, which may occur with any inhaled corticosteroid, include growth retardation in children and adolescents. Physicians should closely follow the growth of adolescents taking long-term corticosteroids and weigh the benefits of asthma control against the possible risk of growth suppression.

Systemic effects of corticosteroids: May occur with any inhaled corticosteroid and include Cushing's syndrome, Cushingoid features and adrenal suppression, decrease in bone mineral density, cataracts, and glaucoma. Any inhaled corticosteroid should be titrated to the lowest dose at which effective control is maintained.

Treatment cessation: Maintenance treatment with ICS should not be stopped abruptly, but tapered gradually under supervision.

Other relevant warnings and precautions:

• Cardiovascular effects
• Candidiasis
• Hyperglycemia, hypokalemia
• Enhanced effect of corticosteroids on patients with hypothyroidism and cirrhosis
• Adrenal insufficiency in patients transferred from systemic steroid
• Decreased bone mineral density
• In rare cases, systemic eosinophilic conditions
• Susceptibility or decreased resistance to infection
• Glaucoma, increased intraocular pressure and cataracts
• Paradoxical bronchospasm
• Potential risk during pregnancy, labour, delivery or nursing
• Special caution in patients >65 years of age with concomitant cardiovascular disease
• Control of asthma should be monitored
• HPA-axis function and hematological status should be assessed periodically
• Not recommended in asthma patients <12 years of age

For more information:

Consult the Product Monograph at symbicort-en.azpm.ca for important information regarding adverse reactions, drug interactions, and dosing. The Product Monograph is also available by calling AstraZeneca Canada at 1-800-668-6000.

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budesonide/formoterol fumarate dihydrate