



Reach for relief. Reach for SYMBICORT[®] TURBUHALER[®].



Indication:

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

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 beta₂-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.

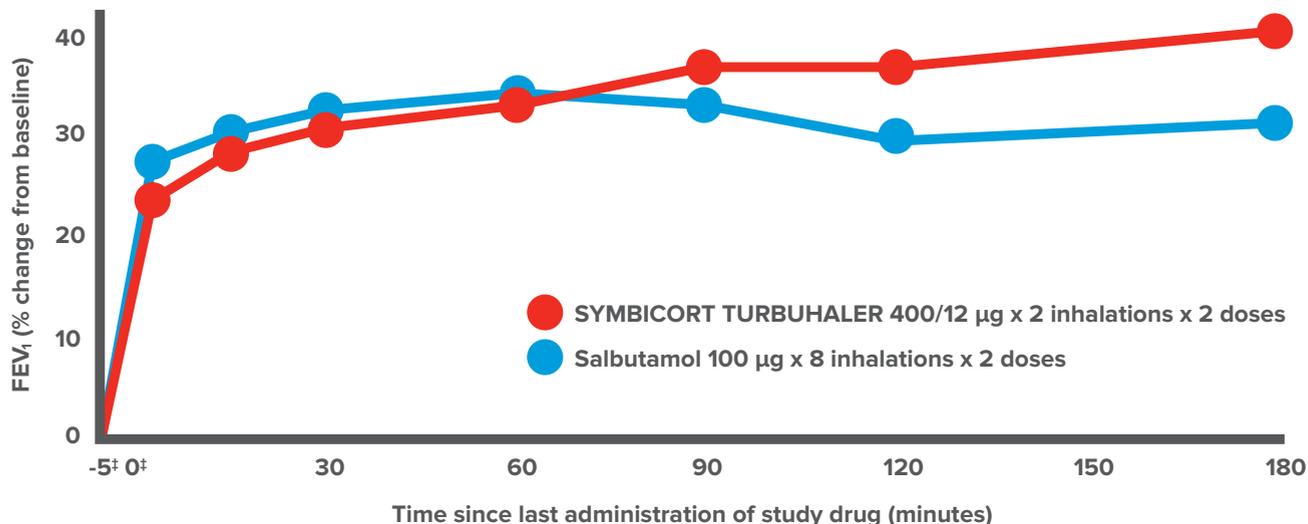
Pr **Symbicort**[®]

budesonide/formoterol
fumarate dihydrate

SYMBICORT TURBUHALER: Onset of effect

SYMBICORT TURBUHALER demonstrated an onset of effect similar to salbutamol (FEV₁; secondary endpoint).^{1,2*}

Comparative clinical significance has not been established.†



Adapted from Balanag VM et al.²

†Study drug was administered at -5 and 0 minutes.²

An increase in FEV₁ with SYMBICORT TURBUHALER lasted at least 90 minutes post administration, similar to salbutamol.

Improvement in FEV₁ with SYMBICORT TURBUHALER vs. salbutamol: 30% vs. 32%; $p=0.66$; primary endpoint.²

*Multicentre, randomized, double-blind, double-dummy, parallel-group 3-hour study. Patients received 2 doses, 5 minutes apart of either SYMBICORT TURBUHALER 400/12 µg 2 inhalations (total dose=1600/48 µg; n=55) or salbutamol 100 µg 8 inhalations (total dose=1600 µg; n=48).²

†Failed to attain superiority on this primary endpoint.²



SYMBICORT TURBUHALER demonstrated a rapid onset of effect similar to salbutamol.^{1,2*}

*Comparative clinical significance has not been established.

Contraindications:

- Hypersensitivity to inhaled lactose.

Most serious warnings and precautions:

Risk of serious asthma-related events — hospitalizations, intubations, and death:

Use of long-acting beta₂-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, cataract, 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
- Not recommended in patients <12 years of age
- 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

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.

References: 1. Symbicort® Turbuhaler® Product Monograph. AstraZeneca Canada Inc. February 8, 2021. 2. Balanag VM et al. Efficacy and safety of budesonide/formoterol compared with salbutamol in the treatment of acute asthma. *Pulm Pharmacol Ther.* 2006;19(2):139–147.