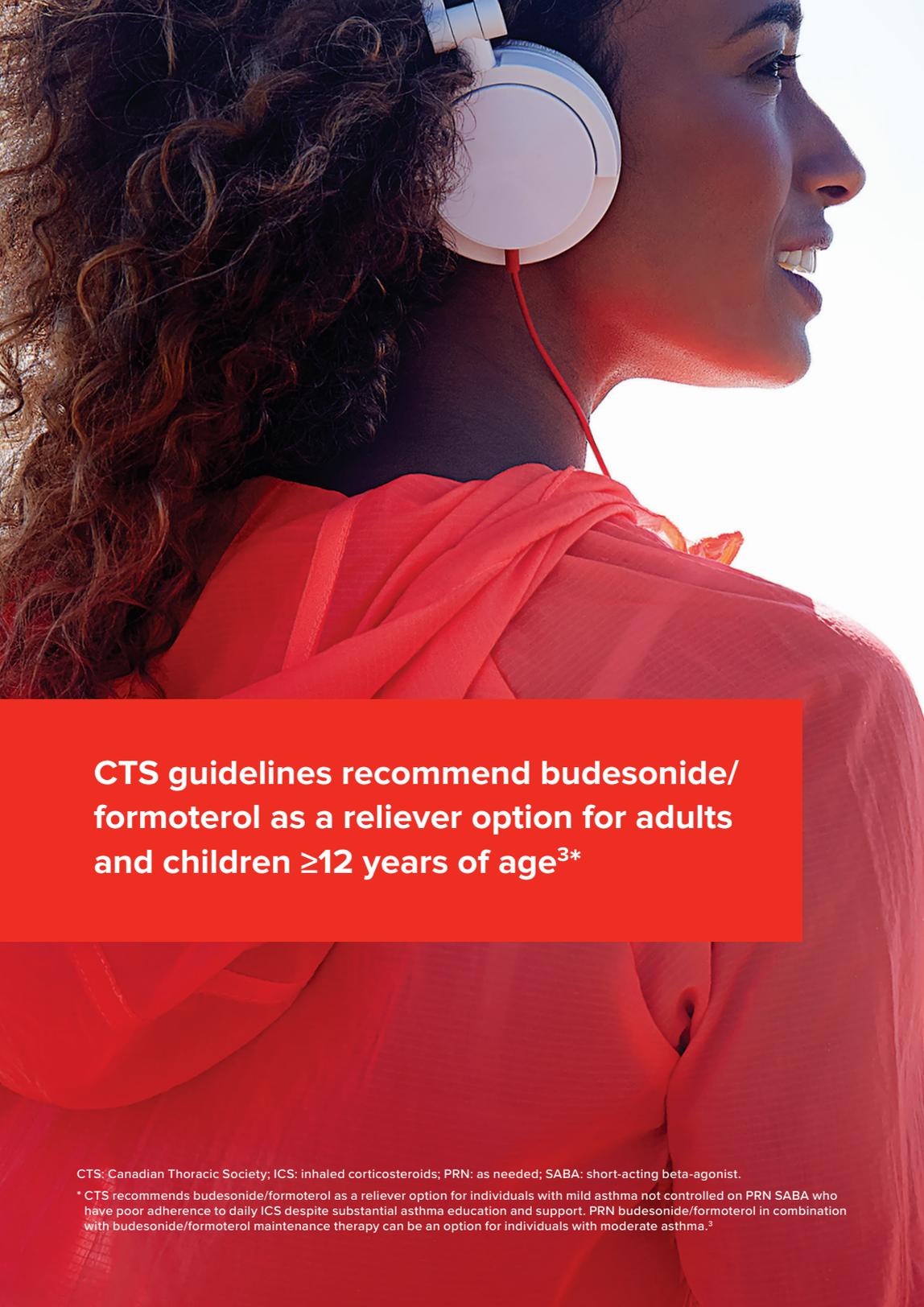




SYMBICORT®.
THE #1
DISPENSED
ICS/LABA.¹

SYMBICORT® TURBUHALER® is indicated for the treatment of asthma in patients 12 years and older with reversible obstructive airways disease.²



**CTS guidelines recommend budesonide/
formoterol as a reliever option for adults
and children ≥ 12 years of age^{3*}**

CTS: Canadian Thoracic Society; ICS: inhaled corticosteroids; PRN: as needed; SABA: short-acting beta-agonist.

* CTS recommends budesonide/formoterol as a reliever option for individuals with mild asthma not controlled on PRN SABA who have poor adherence to daily ICS despite substantial asthma education and support. PRN budesonide/formoterol in combination with budesonide/formoterol maintenance therapy can be an option for individuals with moderate asthma.³

MILD PERSISTENT ASTHMA

SYMBICORT TURBUHALER ANTI-INFLAMMATORY RELIEVER THERAPY: DEMONSTRATED EFFICACY

↑ **34.4% vs. 31.1%**

well-controlled asthma weeks (WCAW)^{2,4*†}

demonstrated with SYMBICORT 200 TURBUHALER Anti-Inflammatory Reliever therapy vs. terbutaline (terb 0.5 mg PRN)

(1° endpoint, $p=0.046$; mean % WCAW: 34.4 vs. 31.1 [OR: 1.14; 95% confidence interval (CI): 1.00, 1.30]).

NOTE: Secondary analysis of the primary endpoint (in terms of WCAW) showed that non-inferiority for asthma symptom control was not met for SYMBICORT 200 TURBUHALER Anti-Inflammatory Reliever therapy vs. budesonide maintenance therapy (bud 200 µg BID + terb 0.5 mg PRN) (lower limit of the 2-sided 95% CI: ≥ 0.8 for non-inferiority; OR: 0.64; $p=NA$).

↓ **64% (0.07 vs. 0.20)**

lower annualized rate of severe exacerbations^{2,4*†}

demonstrated with SYMBICORT 200 TURBUHALER Anti-Inflammatory Reliever therapy vs. terbutaline (terb 0.5 mg PRN)

(2° endpoint, $p<0.001$; annualized exacerbation rate: **0.07** [95% CI: 0.06, 0.09] vs. **0.20** [95% CI: 0.16, 0.24], respectively; RR: 0.36; 95% CI: 0.27, 0.49).

Comparable reduction in annual severe exacerbation rate (0.07 vs. 0.09) demonstrated with SYMBICORT 200 TURBUHALER Anti-Inflammatory Reliever therapy vs. budesonide maintenance therapy (bud 200 µg BID + terb 0.5 mg PRN)

(2° endpoint, $p=0.28$; annualized severe exacerbation rate: **0.07** [95% CI: 0.06, 0.09] vs. **0.09** [95% CI: 0.07, 0.11]; RR: 0.83; 95% CI: 0.59, 1.16).

CI: confidence interval; ICS: inhaled corticosteroid; OR: odds ratio; RR: rate ratio; WCAW: well-controlled asthma weeks.

* SYGMA 1 study: Randomized, double-blind, parallel-group, 52-week study comparing SYMBICORT 200 TURBUHALER Anti-Inflammatory Reliever therapy to terbutaline (0.5 mg PRN) or budesonide maintenance therapy (bud 200 µg BID + terb 0.5 mg) in patients with mild persistent asthma (N=3836 patients).^{2,4}

† WCAW was a composite endpoint capturing asthma symptoms, night-time awakenings, lung function, use of as-needed medication, and prescription of ICS and/or systemic glucocorticosteroid treatment for asthma. WCAW had 3 possible values: well-controlled, not-well-controlled, and missing.²

‡ Severe exacerbation was defined as worsening asthma leading to the use of systemic glucocorticoids for ≥ 3 days, inpatient hospitalization, or an emergency department visit leading to the use of systemic glucocorticoids.⁴



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

**1 INHALER = CONTROLLER medication +
RELIEVER medication***

Pharmacodynamic profile

SYMBICORT TURBUHALER demonstrated rapid onset of effect*

- SYMBICORT TURBUHALER and the short-acting bronchodilator salbutamol have been shown to have similarly rapid onsets of effect.²

* Clinical significance has not been established.

MODERATE TO SEVERE ASTHMA

SYMBICORT TURBUHALER ANTI-INFLAMMATORY RELIEVER PLUS MAINTENANCE THERAPY: DEMONSTRATED EFFICACY

↓ 39% (125 vs. 208)

fewer severe exacerbations^{2,5*}

demonstrated with SYMBICORT 200 TURBUHALER Anti-Inflammatory Reliever plus Maintenance therapy vs. fluticasone/salmeterol maintenance + terbutaline

(2° endpoint, $p < 0.001$; # of severe exacerbations: **125 vs. 208**).

* COMPASS study: Randomized, double-blind, double-dummy, parallel-group, 6-month study comparing SYMBICORT 200 TURBUHALER Anti-Inflammatory Reliever plus Maintenance therapy (SYMBICORT 200 TURBUHALER 1 inhalation BID + SYMBICORT 200 TURBUHALER PRN) to fluticasone/salmeterol maintenance + terbutaline (flut/salm125/25 µg 2 inhalations BID + terb 0.5 mg PRN) or SYMBICORT 400/12 µg BID Maintenance therapy (SYMBICORT 400/12 µg 1 inhalation BID + terb 0.5 mg PRN) in patients with moderate to severe asthma (N=3335).^{2,5}

† Severe exacerbations were defined as deterioration in asthma resulting in hospitalization or emergency room treatment or the need for oral steroids for ≥3 days (as judged by the investigator).^{2,5}

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.

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 asthma 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. Data on file. AstraZeneca Canada Inc. April 15, 2024. 2. SYMBICORT TURBUHALER Product Monograph. AstraZeneca Canada Inc. February 8, 2021. 3. Yang CL, et al. Canadian Thoracic Society 2021 Guideline update: Diagnosis and management of asthma in preschoolers, children and adults. *Can J Respir Crit Care Sleep Med.* 2021; 5(6):348–361. 4. O'Byrne PM, et al. Inhaled combined budesonide-formoterol as needed in mild asthma. (Symbicort Given as Needed in Mild Asthma [SYGMA] 1 trial). *N Engl J Med.* 2018;378(20):1865–1876. 5. Kuna P, et al. Effect of budesonide/formoterol maintenance and reliever therapy on asthma exacerbations. *Int J Clin Pract.* 2007;61(5):725–736.

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Symbicort[®]
budesonide/formoterol
fumate dihydrate