

Indication and clinical use:

Symbicort® is indicated for the treatment of asthma in patients 12 years and older with reversible obstructive airways disease. In patients with asthma, there are two treatment approaches: Symbicort® Maintenance Therapy, where Symbicort® is taken as regular maintenance treatment with a separate rapid-acting bronchodilator as rescue, and Symbicort Maintenance and Reliever Therapy (SMART®), where Symbicort® is taken as regular maintenance treatment and as needed in response to symptoms. Symbicort® should not be used in patients whose asthma can be managed by occasional use of a rapid onset, short duration, inhaled beta₂-agonist or in patients whose asthma can be managed by inhaled corticosteroids along with occasional use of a rapid onset, short duration, inhaled beta₂-agonist.

Contraindications:

- Hypersensitivity to inhaled lactose

Most serious warnings and precautions:

Risk of asthma-related death: Long-acting beta₂-agonists (LABA), such as formoterol, one of the active ingredients in Symbicort®, may increase the risk of asthma-related death. This was found with salmeterol and is considered a LABA class effect. LABA may increase the risk of asthma-related hospitalization in pediatric and adolescent patients. It has not been established whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. Therefore, when treating patients with asthma, Symbicort® should only be used for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid, or whose disease severity clearly warrants the initiation of treatment with both an inhaled corticosteroid and LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals, and do not use Symbicort® for patients whose asthma is adequately controlled on low- to medium-dose inhaled corticosteroids.

Rescue medication: Inform patients to have rescue medication available at all times.

Recommended dosage: Do not exceed.

Use in adolescents: Periodic reassessment should be considered as severity of asthma may vary with age.

Other relevant warnings and precautions:

- Treatment should not be stopped abruptly
- Cardiovascular effects
- Candidiasis
- Hyperglycemia, hypokalemia
- Enhanced effect of corticosteroids on patients with hypothyroidism and cirrhosis
- Adrenal insufficiency in patients transferred from systemic steroid
- Susceptibility or decreased resistance to infection
- Paradoxical bronchospasm
- Potential risk during pregnancy, labour, delivery or nursing
- Control of asthma should be monitored

For more information:

Consult the Product Monograph at azinfo.ca/symbicort/pm796 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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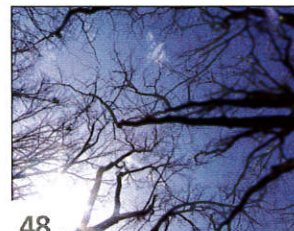
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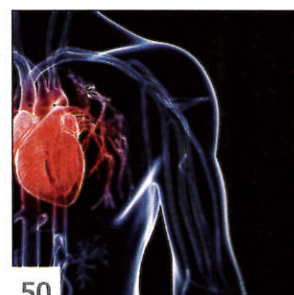
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