



Symbicort[®] (budesonide/formoterol fumarate dihydrate) – Expanded Indication

- On January 30, 2017, [AstraZeneca announced](#) the [FDA approval](#) of [Symbicort \(budesonide/formoterol fumarate dihydrate\)](#), for the treatment of asthma in patients 6 years of age and older.
 - Previously, Symbicort was indicated for the treatment of asthma in patients 12 years of age and older.
 - Symbicort is not indicated for the treatment of acute bronchospasm.
- Symbicort 160 mcg/4.5 mcg is also indicated for the maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
- Efficacy for the expanded indication of Symbicort was established in a 12-week study of 184 pediatric patients (6 to < 12 years of age) with asthma randomized to Symbicort 80 mcg/4.5 mcg vs. budesonide 80 mcg inhaled twice daily. The primary endpoint was change from baseline to week 12 in 1-hour post-dose FEV₁.
 - There was a statistically significant increase from baseline in FEV₁ in patients taking Symbicort vs. budesonide (mean difference = 0.12 L; [95% CI: 0.03, 0.20]).
 - There was also greater improvement in 1-hour post-dose peak expiratory flow (PEF) for the Symbicort vs. budesonide patients (mean difference = 25.5 L/min; [95% CI: 10.9, 40]).
 - In addition, clinical support for use of Symbicort in children was provided by a budesonide confirmatory study and a formoterol dose finding study.
- Symbicort carries a boxed warning for asthma-related death.
- The most common adverse events (≥ 3%) with Symbicort use in asthma patients were nasopharyngitis, headache, upper respiratory tract infection (URTI), pharyngolaryngeal pain, sinusitis, influenza, back pain, nasal congestion, stomach discomfort, vomiting, and oral candidiasis.
- The most common adverse events (≥ 3%) with Symbicort use in COPD patients were nasopharyngitis, oral candidiasis, bronchitis, sinusitis, and URTI.
- The recommended dose of Symbicort for the treatment of asthma in patients aged 6 to < 12 years is 2 inhalations of Symbicort 80 mcg/4.5 mcg twice daily.
 - For the treatment of asthma in patients 12 years of age and older, the recommended dose is 2 inhalations of Symbicort 80 mcg/4.5 mcg or 160 mcg/4.5 mcg twice daily.
 - The maximum recommended dose of Symbicort in patients 12 years of age and older is 2 inhalations of the 160 mcg/4.5 mcg strength twice daily.
- The recommended dose of Symbicort for the treatment of COPD is 2 inhalations of Symbicort 160 mcg/4.5 mcg twice daily.



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