First generic of symbicort receives FDA approval

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The U.S. Food and Drug Administration approved the first generic of

Symbicort (budesonide and formoterol fumarate dihydrate) Inhalation Aerosol to treat asthma in patients 6 years and older and for maintenance treatment in patients with chronic obstructive pulmonary disease (COPD), the agency announced March 15.

The FDA notes that the generic metered-dose inhaler should not be used to treat acute asthma attacks. For the COPD indication, the generic is approved for maintenance treatment of airflow obstruction and for reducing exacerbations in patients with chronic bronchitis and/or emphysema.

The drug-device combination product, which contains both budesonide and formoterol fumarate dihydrate, should be administered as two inhalations two times per day about 12 hours apart to prevent symptoms such as wheezing in asthma and to improve breathing in COPD. Two strengths of the inhaler have been approved: 160/4.5 mcg/actuation and 80/4.5 mcg/actuation.

For those with asthma, the most commonly reported side effects with budesonide and formoterol fumarate dihydrate oral inhalation aerosol are nasopharyngitis, headache, upper respiratory tract infection, pharyngolaryngeal pain, sinusitis, influenza, back pain, nasal congestion, stomach discomfort, vomiting, and oral candidiasis. For those with COPD, commonly reported side effects include nasopharyngitis, oral candidiasis, bronchitis, sinusitis, and upper respiratory tract infection.

Approval of the generic budesonide and formoterol fumarate dihydrate inhalation aerosol was granted to Mylan Pharmaceuticals Inc.

More information: More Information