

Generic version of popular asthma inhaler wins FDA approval

January 31 2019



(HealthDay)—The first generic version of the widely used Advair

Diskus inhaler for asthma and chronic obstructive pulmonary disease (COPD) has won U.S. Food and Drug Administration approval.

This approval "is part of our longstanding commitment to advance access to lower cost, high-quality generic alternatives," said Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research.

"People living with [asthma](#) and COPD know too well the critical importance of having access to the treatment they need to feel better. Today's approval will bring more competition to the market, which will ultimately benefit the patients who rely on this drug," Woodcock said Wednesday in an agency news release.

The new inhaler, from drug maker Mylan, contains fluticasone propionate and salmeterol inhalation powder. It's approved for twice-daily treatment of asthma in patients aged 4 years and older. In COPD cases, it's approved for maintenance treatment of airflow obstruction and reducing exacerbations.

Asthma is a [chronic lung disease](#) that inflames and narrows the airways. More than 26 million people in the United States are known to have it, including about 7 million children, the FDA noted.

COPD is a progressive lung disease that affects breathing and often worsens over time. Symptoms can include coughing that produces large amounts of mucus, wheezing, shortness of breath, and chest tightness.

The inhaler comes in three strengths: fluticasone propionate 100 mcg/salmeterol 50 mcg; fluticasone propionate 250 mcg/salmeterol 50 mcg; and fluticasone propionate 500 mcg/salmeterol 50 mcg.

In asthma patients, the most common side effects of this combination

treatment are: upper-respiratory tract infection or inflammation; swelling in the back of the throat; hoarse voice or trouble speaking; oral thrush, also called candidiasis; bronchitis; cough; headaches; nausea and vomiting.

In COPD patients, the most common side effects are: pneumonia; oral candidiasis; throat irritation; hoarse voice or trouble speaking; viral respiratory infections; headaches; and musculoskeletal pain.

More information: SOURCE: U.S. Food and Drug Administration, news release, Jan. 30, 2019

The American Academy of Allergy, Asthma & Immunology has more on [inhaled asthma medications](#).

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Citation: Generic version of popular asthma inhaler wins FDA approval (2019, January 31) retrieved 7 May 2024 from

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