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Teva Announces FDA approval of AirDuoÃ?Â® DigihalerÃ¢â??Â¢

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The First Digital Maintenance Asthma Inhaler Therapy with Integrated Sensors Joins Teva's Digital Rescue Inhaler Therapy to Provide Patients with Technology to Track Treatment Use



Teva Pharmaceutical Industries Ltd. announced that the U.S. Food and Drug Administration (FDA) has approved AirDuo® Digihaler™ (fluticasone propionate 113 mcg and salmeterol 14 mcg) Inhalation Powder, a combination therapy digital inhaler with built-in sensors that connects to a companion mobile application to provide information on inhaler use to people with asthma. AirDuo® Digihaler™ is indicated for the treatment of asthma in patients aged 12 years and older. AirDuo® Digihaler™ is not used to relieve sudden breathing problems and won't replace a rescue inhaler.

"We are thrilled to be able to expand our Digihaler™ portfolio to now include a maintenance treatment," said Tushar Shah, M.D., Global Head of Specialty Clinical Development at Teva Pharmaceuticals. "With this approval, patients can now track how frequently they are using their inhalers. Granting patients the ability to track their maintenance inhaler use may help inform conversations with their doctors about treatment adherence and proper technique."

Like ProAir® Digihaler™ (albuterol sulfate 117 mcg) inhalation powder, indicated for the treatment or prevention of bronchospasm in patients aged four years and older with reversible obstructive airway disease, and for prevention of exercise-induced bronchospasm (EIB) in patients four years and older, AirDuo® Digihaler™ contains built-in sensors that detect when the inhaler is used and measure inspiratory flow rates. This data is then sent to a companion mobile app using Bluetooth® Wireless Technology so that patients can review their data over time, and if desired, share it with their healthcare providers. Patients can also schedule reminders on their smartphone to take their AirDuo® Digihaler™ as prescribed.

The approval of AirDuo® Digihaler™ is based on the review of the supplemental new drug application (sNDA) submitted by Teva to the FDA. AirDuo® Digihaler™ combines a breath-actuated, multi-dose dry powder inhaler with fluticasone propionate, an inhaled corticosteroid (ICS) medicine that may help to decrease inflammation in the lungs, which can lead to breathing problems, and salmeterol, a long acting beta$_2$ adrenergic agonist (LABA), which helps the muscles around the airways in the lungs stay relaxed in order to prevent symptoms. AirDuo® Digihaler™ contains salmeterol. LABA medicines such as salmeterol when used alone increase the risk of hospitalizations and death from asthma problems.

AirDuo® Digihaler™ contains an ICS and a LABA. When an ICS and a LABA are used together, there is not a significant increased risk in hospitalizations and death from asthma problems.