Generic Name:
Aclidinium bromide/formoterol fumarate
Trade Name:
Duaklir
Company:
Circassia Pharmaceuticals
Notes:

Circassia Pharmaceuticals announced FDA approval of aclidinium bromide/formoterol fumarate for maintenance treatment of chronic obstructive pulmonary disease (COPD) under the trade name Duaklir.

The agent is a fixed-dose combination of the long-acting muscarinic antagonist (LAMA) aclidinium bromide (400 mcg) and long-acting beta-agonist (LABA) formoterol fumarate (12 mcg). It is administered twice daily via the breath-actuated inhaler Pressair.

Approval was based on a broad clinical database, including data from three Phase III studies, ACLIFORM, AUGMENT, and AMPLIFY. The label also includes clinical data from the Phase IV ASCENT study, which shows aclidinium therapy is effective at reducing COPD exacerbations. As a result, Duaklir is the only twice-daily LAMA/LABA in the United States with COPD exacerbation data included in its prescribing information.

Circassia plans to launch Duaklir in the United States in the second half of 2019.

Medication Monitor Categories:
Supplemental Approvals