Generic Name:
Aclidinium bromide
Trade Name:
Tudorza Pressair
Company:
Forest Laboratories
Notes:

Forest Laboratories and Almirall announced FDA approval of aclidinium bromide inhalation powder for the long-term maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. This new twice-daily inhalation is a long-acting anticholinergic, also referred to as a long-acting muscarinic antagonist. It produces bronchodilation by inhibiting acetylcholine's effect on muscarinic receptors in the airway smooth muscle.

This novel agent is administered using Pressair, a multiple-dose dry powder inhaler which delivers 60 doses of aclidinium bromide powder for inhalation. The Pressair inhaler has a colored control window and audible "click" which confirm successful inhalation of the dose, as well as a dose indicator to let patients know how many doses remain in the inhaler.

Approval was based on data from three confirmatory pivotal placebo-controlled trials. These two 12-week and one 24-week trials evaluated the efficacy and safety of aclidinium bromide 400 µg twice daily in 1,276 patients who had a clinical diagnosis of COPD, were 40 years or older, had a smoking history of at least 10 pack?years, a forced expiratory volume in 1 s (FEV_1) of at least 30% and less than 80% of predicted normal value, and a ratio of FEV_1 over forced vital capacity of less than 0.7. In all three pivotal trials, aclidinium bromide demonstrated statistically significant improvements in bronchodilation as measured by change from baseline in morning predose trough FEV_1 at 12 weeks (the primary endpoint) compared with placebo. The mean 12-week predose FEV_1 improvements compared with placebo were 0.12 L, 0.07 L, and 0.11 L in the three trials, with a 24-week improvement of 0.13 L in the 6-month trial.

The most common adverse reactions that occurred in the active treatment group, compared with placebo, were headache (6.6% vs 5.0%), nasopharyngitis (5.5% vs 3.9%), and cough (3.0% vs 2.2%). In addition, data from three long-term safety studies evaluating 891 patients treated with aclidinium bromide 400 µg twice daily for 40 weeks to 52 weeks reported similar adverse events, with no new safety findings compared to the placebo-controlled trials.

According to the manufacturer, the product is expected to be available to wholesalers in the fourth calendar quarter of 2012.

Medication Monitor Categories:
New Drug Approvals
Use:

Long-term maintenance treatment of COPD