



COPD Drug Tudorza Pressair Wins FDA Approval

Monday 30 July 2012 - 5am PST

 COPD

 Regulatory Affairs / Drug Approvals

 Respiratory / Asthma

Featured Article 

Tudorza Pressair, a drug for the treatment of chronic obstructive pulmonary disease (COPD), has received approval from the US Food and Drug Administration (FDA).

The FDA announced last week that it had approved the acclidinium bromide inhalation powder, for the long-term maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic [bronchitis](#) and [emphysema](#).

Bronchospasm is where the muscle walls of the airways in the lung (bronchioles) suddenly constrict, causing mild to severe difficulty in breathing.

Tudorza Pressair, distributed by Forest Laboratories subsidiary Forest Pharmaceuticals of St. Louis, is a long-acting dry powder that is inhaled twice a day to help the muscles of the large airways stay relaxed and open to improve airflow.

The product is a multiple-dose inhaler, Pressair, that delivers 60 doses of acclidinium bromide powder.

The agent is a type of anticholinergic known as a long-acting M3 muscarinic antagonist.

Howard Solomon, Chairman, Chief Executive Officer, and President of Forest Laboratories said:

"As the first long-acting inhaled anticholinergic agent approved in over 8 years for COPD, **Tudorza will be an important treatment option available for the millions of patients living with this serious disease.**"

The company expects to be making the drug available to wholesalers in the fourth quarter of 2012.

COPD

COPD is a common, serious, debilitating and progressive lung disease where the airflow to and from the lungs becomes increasingly limited. As it gets worse, breathing becomes increasingly difficult.

COPD is currently the third leading cause of death in the United States. The World Health Organization (WHO) has described it as a global epidemic, with 64 million worldwide living with the disease.

90% of cases result from smoking. Symptoms include chest tightness, increasing difficulty breathing, becoming breathless, too much sputum or phlegm, and a chronic cough.

There is currently no cure, and doctors don't know how to reverse the damage to the airways and lungs.

As the disease progresses the airways in the lungs lose their elasticity, produce excess mucus and become thick and inflamed. This leads to air trapping, where air can't be exhaled because the tiny air sacs, the alveoli, are over-inflated, and also to pulmonary emphysema (holes in the lung filled with air that reduce the lung surface area).

People with COPD find their quality of life can be greatly impaired, as even daily activities such as walking up a short flight of stairs, or carrying shopping or a suitcase, can become very difficult.

Early detection is the key to successful treatment of COPD, so scientists are always looking for ways to spot the symptoms earlier, before people start feeling them. For instance, recently, an Austrian team [reported the possibility of a blood test](#) that could help detect COPD.

In the meantime, people with COPD rely on drugs to alleviate the symptoms, as Curtis Rosebraugh, director of the Office of Drug Evaluation II in the Center for Drug Evaluation and Research at the FDA, explains:

"COPD is a serious disease that gets worse over time."

"The availability of long-term maintenance drugs for COPD provides additional treatment options for the millions of people who suffer with this debilitating disease," he added.

Clinical Trials and Side Effects

The FDA reviewed three randomized, placebo-controlled confirmatory clinical trials (two 12-week trials and one 24-week trial) that tested the safety and efficacy of Tudorza Pressair (400 mcg twice daily).

The trials covered a total of 1,276 patients aged 40 and over, with a clinical diagnosis of COPD, and a smoking history of at least one pack a day for 10 years.

All three trials showed taking Tudorza Pressair significantly improved bronchodilation, compared to placebo.

A Forest company statement reports:

"Mean peak improvements in lung function (FEV1) assessed after the first dose of Tudorza were similar to those observed at week 12 in each study."

"In two of the three trials, patients treated with Tudorza Pressair also used less daily rescue albuterol compared to placebo treated patients," they add.

The FDA says although the trials showed no serious side effects from using the drug (the most common ones

were [headache](#), [inflammation](#) of the nasal passage (nasopharyngitis), and cough), they warn that:

"**Tudorza Pressair may cause serious side effects**, including paradoxical bronchospasm, new or worsened increased pressure in the eyes (acute narrow-angle [glaucoma](#)), or new or worsened urinary retention.

"Tudorza Pressair should not be used as a rescue therapy to treat sudden breathing problems (acute bronchospasm) and is not recommended for people younger than 18 years," they add.

For further information about the drug and its side effects, see the [Tudorza website](#).

Additional source: [FDA Newsroom](#); [Forest Laboratories News Center](#)

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References

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Paddock, Catharine. "COPD Drug Tudorza Pressair Wins FDA Approval." *Medical News Today*. MediLexicon, Intl., 30 Jul. 2012. Web.

15 Jun. 2014. <<http://www.medicalnewstoday.com/articles/248417>>

APA

Paddock, C. (2012, July 30). "COPD Drug Tudorza Pressair Wins FDA Approval." *Medical News Today*. Retrieved from <http://www.medicalnewstoday.com/articles/248417>.

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