



Trelegy Ellipta (FF/UMEC/VI) Media Factsheet

ABOUT COPD & THE IMPACT OF THE DISEASE

Chronic Obstructive Pulmonary Disease (COPD) is a complex and progressive lung disease that limits airflow to the lungs, interfering with normal breathing. It affects 24 million people in the US⁸.

For people living with COPD, the inability to breathe normally can consume their daily lives and make simple activities, like walking upstairs, an everyday struggle.

Long-term exposure to inhaled irritants that damage the lungs and the airways are usually the cause of COPD. Cigarette smoke, breathing in second hand smoke, air pollution, chemical fumes or dust from the environment or workplace can all contribute to COPD. Most people who have COPD are at least 40 years old when symptoms begin.²

Every person with COPD is different, with different needs, different challenges and different goals. Understanding this and providing support to help meet these needs is the foundation of GSK's work.

ABOUT TRELEGY ELLIPTA

Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol 100/62.5/25mcg) is the first and only approved once-daily, single inhaler triple therapy for COPD. It is comprised of fluticasone furoate (FF), an inhaled corticosteroid (ICS); umeclidinium (UMEC), a long-acting muscarinic antagonist (LAMA); and vilanterol (VI), a long-acting beta2-adrenergic agonist (LABA), delivered in a single daily inhalation from GSK's Ellipta inhaler.⁵

Trelegy Ellipta is indicated for COPD patients already on Breo Ellipta (FF/VI) for whom additional lung function with Incruse Ellipta (VI) is desired, or for patients who are already receiving Breo Ellipta and Incruse Ellipta. Trelegy Ellipta is not indicated for relief of acute bronchospasm or the treatment of asthma.

TRELEGY ELLIPTA is a combination inhaled corticosteroid/anticholinergic/long-acting beta2 adrenergic agonist indicated for the long-term, once-daily, maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, who are on a fixed-dose combination of fluticasone furoate and vilanterol for airflow obstruction and reducing exacerbations in whom additional treatment of airflow obstruction is desired or for patients who are already receiving on umeclidinium and a fixed-dose combination of fluticasone furoate and vilanterol.

With the introduction of Trelegy Ellipta, people with COPD who are on Breo Ellipta and need additional lung function, or who are taking triple therapy using Breo Ellipta and Incruse Ellipta in multiple inhalers, now have the option of getting the three medicines they need from Breo and Incruse delivered once a day in a single inhaler.

MODE OF ACTION

Trelegy Ellipta contains two types of bronchodilators commonly used in the treatment of COPD – LAMAs and LABAs. Bronchodilators work by relaxing airway muscles and reducing airway constriction to improve airflow to and from the lungs, which can make it easier for patients to breathe. In addition, Trelegy Ellipta contains an ICS which can reduce inflammation in the airways.

EFFICACY IN CLINICAL TRIALS

FDA's approval of Trelegy Ellipta is based primarily on efficacy data from two clinical trials in which patients took FF/VI and UMEC in separate inhalers; longer term safety data from previous clinical studies of FF, VI, and UMEC; and other clinical and laboratory data showing that delivery of FF, VI, and UMEC from the single Trelegy inhaler is comparable to delivery from the separate inhalers used in the various clinical studies.

Phase III studies (200109 and 200110) showed that the addition of Incruse to Breo resulted in a statistically significant improvement in lung function compared to patients receiving Breo plus placebo.

200109: The most frequently reported adverse events (greater than or equal to 3% in any treatment group) were headache, nasopharyngitis, back pain, dysgeusia (an abnormal taste or change in taste), cough, diarrhoea and influenza.

200110: The most frequently reported adverse events (greater than or equal to 3% in any treatment group) were nasopharyngitis, headache and back pain.

IMPORTANT SAFETY INFORMATION

The following ISI is based on the Highlights section of the US Prescribing Information for Trelegy Ellipta. Please consult the full Prescribing Information for all the labelled safety information for Trelegy Ellipta.

Long-acting beta₂-adrenergic agonists (LABA), such as vilanterol, increase the risk of asthma-related death. A placebo-controlled trial with another LABA (salmeterol) showed an increase in asthma related deaths. This finding with salmeterol is considered a class effect of all LABA. The safety and efficacy of TRELEGY ELLIPTA in patients with asthma have not been established. TRELEGY ELLIPTA is not indicated for the treatment of asthma.

Trelegy Ellipta is contraindicated in patients with severe hypersensitivity to milk proteins or any of the ingredients.

Trelegy Ellipta should not be initiated in patients experiencing episodes of acutely deteriorating COPD. Do not use TRELEGY ELLIPTA to treat acute symptoms.

Trelegy Ellipta should not be used in combination with other medicines containing LABA because of risk of overdose.

Candida albicans infection of the mouth and pharynx has occurred in patients treated with fluticasone furoate, a component of Trelegy Ellipta. Monitor patients periodically. Advise the patient to rinse his/her mouth with water without swallowing after inhalation to help reduce the risk.

There is an increased risk of pneumonia in patients with COPD taking TRELEGY ELLIPTA. Monitor patients for signs and symptoms of pneumonia.

Patients who use corticosteroids are at risk for potential worsening of infections (e.g. existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex). Use TRELEGY ELLIPTA with caution in patients with these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients.

There is a risk of impaired adrenal function when transferring from systemic corticosteroids. Taper patients slowly from systemic corticosteroids if transferring to TRELEGY ELLIPTA.

Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage of TRELEGY ELLIPTA in susceptible individuals. If such changes occur, consider appropriate therapy.

If paradoxical bronchospasm occurs, discontinue TRELEGY ELLIPTA and institute alternative therapy.

Use TRELEGY ELLIPTA with caution in patients with cardiovascular disorders because of beta-adrenergic stimulation.

Assess patients for decrease in bone mineral density initially and periodically thereafter after prescribing TRELEGY ELLIPTA.

Close monitoring for glaucoma and cataracts is warranted in patients taking TRELEGY ELLIPTA. Worsening of narrow-angle glaucoma may occur. Use with caution in patients with narrow-angle glaucoma and instruct patients to contact a healthcare provider immediately if symptoms occur.

Worsening of urinary retention may occur in patients taking TRELEGY ELLIPTA. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a healthcare provider immediately if symptoms occur.

Use TRELEGY ELLIPTA with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis.

Be alert to hypokalemia and hyperglycemia in patients taking TRELEGY ELLIPTA.

The most common adverse reactions reported for TRELEGY ELLIPTA (incidence $\geq 1\%$) are headache, back pain, dysgeusia, diarrhea, cough, oropharyngeal pain, and gastroenteritis.

REFERENCES

1. Global Initiative for Chronic Obstructive Lung Disease Global Initiative for Chronic Obstructive Lung Disease. Pocket guide to COPD diagnosis, management, and prevention. Available at: <http://goldcopd.org/wp-content/uploads/2016/12/wms-GOLD-2017-Pocket-Guide.pdf>
2. GSK data on file from Adelphi Disease Specific Programme, 2016
3. Hurst et al. Susceptibility to Exacerbation in Chronic Obstructive Pulmonary Disease. *The New England Journal of Medicine*. 2010;3;1128-38
4. Barnes et al. COPD and exacerbations: Patient insights from the global Hidden Depths of COPD Survey. *BMC Pulmonary Medicine* 2013; 13:54
5. Trelegy SmPC
6. What Is COPD? (2017, April 28). Retrieved August 09, 2017, from <https://www.nhlbi.nih.gov/health/health-topics/topics/copd/>
7. Simeone JC, Luthra R, Kaila S, et al. Initiation of triple therapy maintenance treatment among patients with COPD in the US. *Int J Chron Obstruct Pulmon Dis*. 2017;12:73-83.
8. Brusselle G, Price D, Gruffydd-jones K, et al. The inevitable drift to triple therapy in COPD: an analysis of prescribing pathways in the UK. *Int J Chron Obstruct Pulmon Dis*. 2015;10:2207-17.