

Generic: fluticasone furoate/ umeclidinium/ vilanterol (FDA approved 09/18/2017)

Company: GlaxoSmithKline and Innoviva

Agent for: Chronic obstructive pulmonary disease (COPD)

Indications: Maintenance treatment of patients with COPD, including chronic bronchitis and/or emphysema, who are on a fixed-dose combination of fluticasone furoate and vilanterol or for patients who are already receiving umeclidinium and a fixed dose combination of fluticasone furoate and vilanterol

Mechanism of Action: Fluticasone furoate is an ICS, umeclidinium is a LAMA and vilanterol is a LABA. LAMAs and LABAs are bronchodilators that relax airways and reduce airway constriction to improve airflow to and from the lungs. ICS can reduce the inflammation in the airways

COMPARABLE DRUG: Bronchodilators (albuterol, levalbuterol, ipratropium, aclidiuim), Daliresp, Corticosteroids (prednisone), Advair, Symbicort, Breo, Anoro.

COST PER MONTH (WAC) FOR TRIPLE THERAPY

TRELEGY ELLIPTA (100/62.5/25 MCG) = \$530.00

BREO (100/25 MCG) + INCRUSE (62.5 MCG) = \$646

ANORO(62.5/25 MCG) + ARNUITY (100 OR 200 MCG) = \$527 - \$581

ADVAIR (250/50MCG + SPIRIVA (18MCG) = \$729.60

BEVESPI (9/4.8MCG) + PULMICORRT (180MCG) = \$768-\$1,200

ADVANTAGES:

- First and only once-daily single inhaler triple therapy approved in the US for maintenance treatment of COPD
- Reduces the need for multiple inhalers
- Improves lung function and reduces attacks more than two-drug combinations in clinical trials

DISADVANTAGES:

- Not intended for patients with rapidly deteriorating or potentially life-threatening episodes of COPD.
- Not indicated for treatment of asthma or acute bronchospasms.

MOST IMPORTANT RISKS/ADVERSE EVENTS: Vilanterol is a LABA, which increase the risk of asthma related death. The safety and efficacy of Trelegy Ellipta in patients with asthma has not been established.

MOST COMMON ADVERSE EVENTS: Most common adverse reactions are headache, back pain, diarrhea, cough, oropharyngeal pain, dysguesia (distortion of taste) and gastroenteritis (stomach flu).

USUAL DOSAGE: One inhalation once daily by the orally inhaled route. After inhalation, the patient should rinse their mouth with water without swallowing to reduce the risk of oropharyngeal candidiasis. Trelegy Ellipta should be used at the same time everyday.

PRODUCT: Product is an inhalation powder intended for oral inhalation only. Powder is contained in a disposable light grey and beige plastic inhaler in two foil blister strips. One strip contains 100 mcg of fluticasone furoate and the other strip contains 62.5 mcg of umeclidinium and 25 mcg of vilanterol. Each inhaler has 60 blisters, which allows for 30 inhalations. Should be stored at room temperature between 20°C to 25°C (68°F to 77°F) and away from sunlight or direct heat. Moisture-protective foil tray should not be opened until immediately before initial use. Discard 6 weeks after opening foil tray or when counter reaches "0", whichever comes first.

COMMENTS: COPD is a disease of the lungs that includes chronic bronchitis and/or emphysema and limits airflow to the lungs. It affects about 384 million people worldwide. It is usually caused by long-term exposure to inhaled irritants that damage the lungs and airways. Symptoms can include chronic cough, wheezing, or shortness of breath. COPD is diagnosed using a breathing test called spirometry. Current treatments are used to reduce the shortness of breath, control coughing and wheezing, and prevent flare-ups. In clinical trials, patients were studied for 12 weeks and there was a statistically significant increase in expiratory volume in patients on Trelegy Ellipta compared to those on placebo. Other studies have shown that Trelegy Ellipta reduced the rate of moderate to severe exacerbations by 15% or 25% compared to Breo Ellipta and Anoro Ellipta, respectively.