Breo Ellipta® (fluticasone furoate/vilanterol) – Expanded indication and new strength

- On May 12, 2023, the FDA approved GSK's Breo Ellipta (fluticasone furoate/ vilanterol), for the maintenance treatment of asthma in patients aged 5 years and older.
    - Breo Ellipta was previously approved for treatment of asthma in patients aged 18 years and older.
    - Breo Ellipta is NOT indicated for the relief of acute bronchospasm.
- Breo Ellipta is also approved for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).
- In addition to the expanded indication, the FDA approved a new lower dosage strength of Breo Ellipta (50 mcg fluticasone furoate and 25 mcg vilanterol per actuation).
- The approval of Breo Ellipta for the expanded indication was based on a randomized, double-blind study in 902 pediatric patients aged 5 to 17 years of age with asthma. The study compared Breo Ellipta vs. fluticasone furoate in patients who were uncontrolled on their current inhaled corticosteroid treatment. The primary endpoint was lung function improvement based on weighted mean forced expiratory volume in 1 second (FEV_1) (0 to 4 hours) at week 12
    - The least squares mean change from baseline in FEV_1 was 406 mL for Breo Ellipta vs. 323 mL for fluticasone furoate (difference of 83, 95% CI: 37, 129).
- The recommended dosage of Breo Ellipta in pediatric patients aged 12 to 17 years with asthma is 100/25 mcg (containing fluticasone furoate 100 mcg and vilanterol 25 mcg), 1 actuation once daily by oral inhalation.
- The recommended dosage of Breo Ellipta in pediatric patients aged 5 to 11 years with asthma is 50/25 mcg (containing fluticasone furoate 50 mcg and vilanterol 25 mcg), 1 actuation once daily by oral inhalation.
- Refer to the Breo Ellipta drug label for dosing for its other uses.