Lexapro® (escitalopram) – Expanded indication

- On May 12, 2023, the FDA approved AbbVie's Lexapro (escitalopram), for the treatment of generalized anxiety disorder (GAD) in adults and pediatric patients 7 years of age and older.
    - Lexapro was previously approved for this indication in adults only.
- Lexapro is also approved for the treatment of major depressive disorder (MDD) in adults and pediatric patients 12 years of age and older.
- The approval of Lexapro for the expanded indication was based on a flexible-dose, placebo-controlled study in pediatric patients 7 to 17 years with GAD. The primary outcome was change from baseline to week 8 in the Pediatric Anxiety Rating Scale (PARS) severity score for GAD.
    - In this study, Lexapro showed a statistically significant treatment difference when compared to placebo on the PARS severity score for GAD (least squares mean difference -1.42, 95% CI: -2.69, -0.15).
- Lexapro carries a boxed warning for suicidal thoughts and behaviors.
- The recommended starting dosage of Lexapro for pediatric patients ages 7 years and older in patients with GAD is 10 mg once daily. Depending on clinical response and tolerability, dosage may be increased to the maximum recommended dosage of 20 mg once daily at an interval of no less than 2 weeks.
    - Refer to the Lexapro drug label for dosing for its other uses.