Cymbalta® (duloxetine) – Expanded indication

- On April 20, 2020, the FDA approved Eli Lilly's Cymbalta (duloxetine), for the treatment of fibromyalgia in adults and pediatric patients 13 years of age and older.
    - Previously, Cymbalta was only approved for this indication in adult patients.
- Cymbalta is also approved for the treatment of:
    - Major depressive disorder in adults
    - Generalized anxiety disorder in adults and pediatric patients 7 years of age and older
    - Diabetic peripheral neuropathic pain in adults
    - Chronic musculoskeletal pain in adults.
- The approval of Cymbalta for the expanded indication was based on a 13-week, placebo-controlled study in 184 pediatric patients aged 13 to 17 years with juvenile fibromyalgia syndrome. Cymbalta was initiated at a dosage of 30 mg once daily for one week and titrated to 60 mg once daily for 12 weeks, as tolerated. The primary endpoint was change from baseline to end-of-treatment on the Brief Pain Inventory – Modified Short Form: Adolescent Version 24-hour average pain severity rating.
    - Cymbalta showed improvement over placebo on the primary endpoint with a p-value of 0.052 from the prespecified primary analysis, and p-values ranging from 0.011 to 0.020 from sensitivity analyses which assigned baseline values to missing assessments of some patients who did not complete the trial for various reasons.
- Cymbalta carries a boxed warning for suicidal thoughts and behavior.
- The recommended starting Cymbalta dosage in pediatric patients 13 to 17 years of age with fibromyalgia is 30 mg orally once daily. The dosage may be increased to 60 mg once daily based on response and tolerability.
    - Refer to the Cymbalta drug label for dosing for all its other indications.