Lyrica® CR (pregabalin) – New formulation approval

- On October 12, 2017, Pfizer announced the FDA approval of Lyrica CR (pregabalin) extended-release tablets, for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN).
    - Efficacy of Lyrica CR has not been established for the management of fibromyalgia or as adjunctive therapy for adult patients with partial onset seizures.
    - Lyrica CR is a Schedule V controlled substance.

- Lyrica® is also available as oral capsules and a solution. Lyrica is indicated for the following:
    - Management of neuropathic pain associated with DPN
    - Management of PHN.
    - Adjunctive therapy for adult patients with partial onset seizures.
    - Management of fibromyalgia.
    - Management of neuropathic pain associated with spinal cord injury.

- The efficacy of Lyrica CR for the management of PHN and DPN was based on the efficacy of Lyrica for these indications along with a randomized study in adults with PHN. The study included a six-week single-blind, dose optimization phase followed by a 13-week double-blind phase.
    - In the PHN study, 73.6% of patients in the Lyrica CR group achieved at least 50% improvement in pain intensity vs. 54.6% percent in the placebo group.

- Warnings and precautions of Lyrica CR include angioedema, hypersensitivity reactions, suicidal behavior and ideation, peripheral edema, dizziness and somnolence, weight gain, risks associated with abrupt or rapid discontinuation, tumorigenic potential, ophthalmological effects, creatine kinase elevations, decreased platelet count, and PR interval prolongation.

- The most common adverse reactions (≥ 4%) of Lyrica CR use were dizziness, somnolence, headache, fatigue, peripheral edema, nausea, blurred vision, dry mouth, and weight gain.

- The recommended starting dosage of Lyrica CR for the management of neuropathic pain associated with DPN and PHN is 165 mg orally once daily with the evening meal. Increase the dose to 330 mg once daily within 1 week based on individual patient response and tolerability.
    - For neuropathic pain associated with DPN, the maximum recommended dose of Lyrica CR is 330 mg once daily.
    - For patients with PHN who do not experience sufficient pain relief following 2 to 4 weeks of treatment with 330 mg once daily and who are able to tolerate Lyrica CR, the dose may be increased to 660 mg once daily.
    - For PHN, the maximum recommended dose of Lyrica CR is 660 mg once daily.
    - Consult the Lyrica CR drug label for recommended dosages when converting from Lyrica capsules or oral solution.

Continued . . .

- Pfizer plans to launch Lyrica CR in January of 2018. Lyrica CR will be available as 82.5 mg, 165 mg, and 330 mg extended-release tablets