Drizalma Sprinkle™ (duloxetine delayed-release) – New indication

- On July 23, 2021, the FDA approved Sun Pharmaceutical's Drizalma Sprinkle (duloxetine delayed-release), for the treatment of fibromyalgia in adults.

- Drizalma Sprinkle 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 neuropathy in adults
  - Chronic musculoskeletal pain in adults.

- Drizalma Sprinkle carries a boxed warning for suicidal thoughts and behaviors.

- The recommended Drizalma Sprinkle dosage is 60 mg once daily in adults with fibromyalgia. Begin treatment at 30 mg once daily for 1 week, to allow patients to adjust to Drizalma Sprinkle before increasing to 60 mg once daily. Some patients may respond to the starting dosage. There is no evidence that dosages greater than 60 mg/day confer additional benefit, even in patients who do not respond to a 60 mg/day dosage, and higher dosages were associated with a higher rate of adverse reactions.

  - Additional pediatric use information is approved for Eli Lilly's Cymbalta® (duloxetine delayed-release). However, due to Eli Lilly's marketing exclusivity rights, Drizalma Sprinkle is not labeled with that pediatric information.
    Refer to the Drizalma Sprinkle drug label for dosing for all its other indications.