Drizalma Sprinkle™ (duloxetine) – New formulation approval

- On July 19, 2019, the FDA approved Sun Pharma's Drizalma Sprinkle (duloxetine) delayed-release capsules, for the treatment of major depressive disorder (MDD) in adults; generalized anxiety disorder (GAD) in adults and pediatric patients 7 years to 17 years old; diabetic peripheral neuropathy (DPNP) in adults; and chronic musculoskeletal pain in adults.

- Duloxetine (Cymbalta®) is also available generically as a delayed-release capsule and carries the same indications as Drizalma Sprinkle.

    — The Drizalma Sprinkle capsules can be opened and the contents sprinkled over applesauce or opened and the contents administered via a nasogastric tube.
    — The generic delayed-release capsules should not be opened; they should be swallowed whole.

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

- Drizalma Sprinkle is contraindicated with use of monoamine oxidase inhibitors (MAOIs). An MAOI should not be started within 5 days of stopping Drizalma Sprinkle. In addition, Drizalma Sprinkle should not be used within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, Drizalma Sprinkle should not be started in a patient who is being treated with linezolid or intravenous methylene blue.

- Additional warnings and precautions for Drizalma Sprinkle include hepatotoxicity; orthostatic hypotension, falls and syncope; serotonin syndrome; increased risk of bleeding; severe skin reactions; discontinuation syndrome; activation of mania/hypomania; angle-closure glaucoma; seizures; elevated blood pressure; clinically important drug interactions; hyponatremia; use in patients with concomitant illness; and urinary hesitation and retention.

- The most common adverse reactions (≥ 5% and at least twice the incidence of placebo) with Drizalma Sprinkle use were nausea, dry mouth, somnolence, constipation, decreased appetite, and hyperhidrosis.

- The recommended dose of Drizalma Sprinkle varies depending on the indication. Drizalma Sprinkle should be taken orally with or without food. Drizalma Sprinkle should be swallowed whole (do not chew or crush the capsule). For patients unable to swallow an intact capsule, refer to the drug label for details regarding alternative administration instructions.

Indication	Starting dose	Target dose	Maximum dose
MDD	40 mg/day to 60 mg/day	*Acute treatment*: 40 mg/day (20 mg twice daily) to 60 mg/day (once daily or as 30 mg twice daily) *Maintenance treatment*: 60 mg/day	120 mg/day

Continued . . .

GAD	*Adults*: 60 mg/day *Elderly*: 30 mg/day *Children and adolescents (7 to 17 years old)*: 30 mg/day	*Adults*: 60 mg/day (once daily) *Elderly*: 60 mg/day (once daily) *Children and adolescents (7 to 17 years old)*: 30 to 60 mg/day (once daily)	120 mg/day
DPNP	60 mg/day	60 mg/day (once daily)	60 mg/day
Chronic musculoskeletal pain	30 mg/day	60 mg/day (once daily)	60 mg/day

- Sun Pharma's launch plans for Drizalma Sprinkle are pending. Drizalma Sprinkle will be available as 20 mg, 30 mg, 40 mg, and 60 mg delayed-release capsules.