

FOR IMMEDIATE RELEASE

Sun Pharma Launches Drizalma Sprinkle in the U.S.

- *First and only FDA-approved sprinkle formulation of delayed-release duloxetine capsules*
- *Only formulation of duloxetine that can be swallowed whole, sprinkled on applesauce or administered via nasogastric tube*
- *Third product in company portfolio designed for the 30-35% of long-term care residents who have difficulty swallowing*

Mumbai, India, and Princeton, NJ, October 16, 2019 – Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, “Sun Pharma” including its subsidiaries and/or associate companies) today announced that one of its wholly owned subsidiaries has launched Drizalma Sprinkle™ (duloxetine delayed-release capsules) in the U.S. for oral use. Drizalma Sprinkle is a serotonin and norepinephrine reuptake inhibitor (SNRI) designed for the treatment of various neuro-psychiatric and pain disorders in patients who have difficulty swallowing – a problem that is estimated to affect approximately 30-35% of long-term care residents. The U.S. Food and Drug Administration (FDA) approved Drizalma Sprinkle on July 19, 2019.

The availability of Drizalma Sprinkle expands Sun Pharma’s portfolio of alternative formulation products designed for individuals with swallowing difficulties, the risk of which increases with age and exposure to age-related diseases and conditions - including depression, anxiety, and pain disorders.¹⁻² Drizalma Sprinkle joins Ezallor Sprinkle™ (Rosuvastatin) and Kapspargo Sprinkle™ (metoprolol succinate) extended-release capsules as the third product in Sun Pharma’s US portfolio designed for individuals in long-term care. It is common practice in long-term care facilities to crush medications to ease administration, but crushing tablets introduces additional risks into the administration process.³ The *Joint Commission International Accreditation Standards for Long Term Care* urges facilities to dispense medications in forms that require minimal manipulation.⁴

“The launch of Drizalma Sprinkle is an important milestone for people with difficulty swallowing, as this formulation of duloxetine can facilitate treatment of common neuro-psychiatric disorders while preserving the quality of the medicine,” said Abhay Gandhi, CEO, North America, Sun Pharma. “This launch further underscores our commitment to providing a portfolio of alternative formulation products to treat common diseases – especially in long-term care, where 30-35% of individuals have difficulty swallowing. These patients often encounter medication errors and challenges with medication administration.”

Drizalma Sprinkle is indicated for the treatment of major depressive disorder (MDD) in adults, generalized anxiety disorder (GAD) in adults and pediatric patients 7-17 years old, diabetic peripheral neuropathic pain (DPNP) in adults, and chronic musculoskeletal pain in adults. It is available in four dosage strengths (20mg, 30mg, 40mg, and 60mg). Drizalma Sprinkle is the first and only FDA-

approved formulation of duloxetine that can be swallowed whole, sprinkled on applesauce or administered via nasogastric tube.

Drizalma Sprinkle carries a boxed warning for suicidal thoughts and behaviors. In clinical trials of Drizalma Sprinkle, the most common adverse reactions (in at least 5% of participants and at least twice the incidence of placebo) were nausea, dry mouth, somnolence, constipation, decreased appetite, and hyperhidrosis.

For more information about Drizalma Sprinkle, visit DrizalmaSprinkle.com

INDICATIONS AND USAGE

Drizalma Sprinkle (duloxetine delayed-release capsules) for oral use is indicated for the treatment of major depressive disorder in adults; generalized anxiety disorder in adults and pediatric patients aged 7 to 17 years; diabetic peripheral neuropathy in adults, and chronic musculoskeletal pain in adults.

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS: Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening and for emergence of suicidal thoughts and behaviors.

Contraindications

Serotonin syndrome and MAOIs: Do not use MAOIs intended to treat psychiatric disorders with Drizalma Sprinkle or within 5 days of stopping treatment with Drizalma Sprinkle. Do not use Drizalma Sprinkle within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start Drizalma Sprinkle in a patient who is being treated with linezolid or intravenous methylene blue.

WARNINGS AND PRECAUTIONS

Hepatotoxicity: Hepatic failure, sometimes fatal, has been reported in patients treated with duloxetine delayed-release capsules. Duloxetine delayed-release capsules should be discontinued in patients who develop jaundice or other evidence of clinically significant liver dysfunction and should not be resumed unless another cause can be established. Drizalma Sprinkle should not be prescribed to patients with substantial alcohol use or evidence of chronic liver disease.

Orthostatic Hypotension, Falls, and Syncope: Cases have been reported with duloxetine delayed-release capsules therapy. Syncope and orthostatic hypotension tend to occur within the first week of therapy but can occur at any time during treatment, particularly after dose increases.

Serotonin Syndrome: There is increased risk when coadministered with other serotonergic agents (eg, SSRIs, SNRIs, triptans), but also when taken alone. The concomitant use of Drizalma Sprinkle with MAOIs is contraindicated. Do not initiate Drizalma Sprinkle in a patient who is being treated

with MAOIs such as linezolid or intravenous methylene blue. Monitor all patients taking Drizalma Sprinkle™ for the emergence of serotonin syndrome. If it occurs, discontinue Drizalma Sprinkle and initiate supportive treatment.

Increased Risk of Bleeding: Duloxetine may increase the risk of bleeding events. Concomitant use of NSAIDs, aspirin, other antiplatelet drugs, warfarin, and anticoagulants may increase this risk.

Severe Skin Reactions: Severe skin reactions, including erythema multiforme and Stevens-Johnson Syndrome, can occur with duloxetine. Drizalma Sprinkle should be discontinued at the first appearance of blisters, peeling rash, mucosal erosions, or any other sign of hypersensitivity if no other etiology can be identified.

Discontinuation Syndrome: Adverse reactions after discontinuation of serotonergic antidepressants, particularly after abrupt discontinuation, include nausea, sweating, dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias, such as electric shock sensations), tremor, anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. A gradual reduction in dosage rather than abrupt cessation is recommended whenever possible.

Activation of Mania or Hypomania: In patients with bipolar disorder, treating a depressive episode with duloxetine delayed-release capsules or another antidepressant may precipitate a mixed/manic episode. Use cautiously in patients with bipolar disorder. Prior to initiating treatment with Drizalma Sprinkle, screen patients for any personal or family history of bipolar disorder, mania, or hypomania.

Angle-Closure Glaucoma: Duloxetine may trigger an angle-closure attack in patients with anatomically narrow angles who do not have a patent iridectomy. Avoid use of antidepressants, including Drizalma Sprinkle, in patients with anatomically narrow angles.

Seizures: Drizalma Sprinkle should be prescribed with care in patients with a history of seizure disorder.

Blood Pressure: Monitor blood pressure prior to initiating treatment and periodically throughout treatment

Hyponatremia: Can occur in association with SIADH. Cases of hyponatremia have been reported

Glucose Control in Diabetes: In diabetic peripheral neuropathic pain patients, small increases in fasting blood glucose and HbA1c have been observed

ADVERSE REACTIONS

The most common adverse reactions ($\geq 5\%$ and at least twice the incidence of placebo patients) were nausea, dry mouth, somnolence, constipation, decreased appetite, and hyperhidrosis.

DOSING AND ADMINISTRATION

Drizalma Sprinkle may be taken with or without food. Drizalma Sprinkle may be swallowed whole (do not crush or chew capsule); opened and sprinkled over applesauce; or administered via nasogastric tube.

DRUG INTERACTIONS

- Avoid concomitant use with potent CYP1A2 inhibitors
- Consider dose reduction with concomitant use with CYP2D6 substrates

USE IN SPECIFIC POPULATIONS

Hepatic Impairment: Avoid use in patients with mild, moderate, or severe hepatic impairment

Renal Impairment: Avoid use in patients with severe renal impairment

Pregnancy: Advise patients to notify their healthcare provider if they become pregnant or intend to become pregnant during treatment with Drizalma Sprinkle. Third trimester use may increase risk of symptoms of poor adaptation (respiratory distress, temperature instability, feeding difficulty, hypotonia, tremor, irritability) in the neonate

Please see Full Prescribing Information by clicking [here](#).

About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050)

Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business and a skilled team enables it to deliver high-quality products, trusted by customers and patients in over 100 countries across the world, at affordable prices. Its global presence is supported by manufacturing facilities spread across 6 continents and approved by multiple regulatory agencies, coupled with a multi-cultural workforce comprising over 50 nationalities. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities across multiple R&D centers, with investments of approximately 7% of annual revenues in R&D. For further information, please visit www.sunpharma.com & follow us on Twitter [@SunPharma_Live](https://twitter.com/SunPharma_Live)

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