CRUSHING IS OUT AND SPRINKLING IS IN

ONE ALTERNATIVE FORMULATION TACKLES FOUR COMMON LTC CONDITIONS

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Taking medication should never be a struggle. For too many seniors, that's been the reality for too long.

The elderly are prone to swallowing disorders, often caused by chronic and/or age-related conditions that can plague patients who may also need mental healthcare.

The first and only delayed-release FDA-approved sprinkle formulation of duloxetine, Drizalma Sprinkle™ (duloxetine) delayed-release capsules, is designed to address those concerns, and more, in a single capsule.

Drizalma Sprinkle™ frees staff from the practice of pill crushing and delivers relief from 4 conditions in a formulation that can be swallowed whole, sprinkled over a tablespoon of applesauce, or delivered through a nasogastric tube.

Sprinkle formulations improve the med pass experience for residents and staff.

"Drizalma Sprinkle™ underscores our commitment to providing a portfolio of alternative formulation products to treat common diseases — especially in long-term care, where 40% of individuals have difficulty swallowing," says Mark Hagler, Senior Vice President and Head of Ophthalmics, Oncology and LTC at Sun Pharma. "These patients often encounter medication errors and challenges with medication administration."

Drizalma Sprinkle™ is Sun Pharma's third sprinkle alternative brought to the US market since 2018, each one developed to address conditions common in long-term care. They've quickly become assets for skilled nursing providers.

INDICATIONS AND USAGE

Drizalma Sprinkle™ (duloxetine) delayed-release capsules are 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 Neuropathic Pain (DPNP) in adults
- 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. Treatment 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™

Please see additional Important Safety Information throughout.

Drizalma Sprinkle™ treats both major depressive order and generalized anxiety disorder, which often overlap.

Having duloxetine, a selective serotonin and norepinephrine reuptake inhibitor, in a flexible administration formulation was a much-needed tool.

Many patients with psychiatric conditions or cognitive impairment — whose conditions are often coupled with comorbidities that put them at a higher risk of mortality — may resist taking the medications their doctors prescribe.

"The struggle to take pills can make patients even more closed off or non-compliant," says Manzar Rajput, MD, president of Great Lakes Psychiatric Associates, who has more than 20 years' experience as a geriatric psychiatrist in Michigan. "A sprinkle formulation is a win-win for everyone, really."

"I'm a firm believer in duloxetine and the medication itself."

— Dheeraj Mahajan, MD
Chicago Internal Medicine Practice and Research

AVOID PILL CRUSHING

Many residents may not be able to physically swallow solid medications due to conditions such as Parkinson's disease or stroke. Researchers estimate that 40% or more of assisted living and skilled nursing residents have feeding difficulties or cannot or will not swallow pills.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS (cont'd)

should not be prescribed for patients with substantial alcohol use or evidence of chronic liver disease.

Orthostatic Hypotension, Falls, and Syncope: 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. 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. A post-marketing study showed a higher incidence of postpartum hemorrhage in mothers taking duloxetine. 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 (eg, paresthesias, such as electric shock sensations), tremor, anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. A gradual

Please see additional Important Safety Information throughout.

To accomodate, many facilities turn to pill crushing, which can introduce additional variables into the administration process. The Joint Commission urges facilities to dispense medications in forms that require minimal manipulation.

Dheeraj Mahajan, MD, is founder, president, and CEO of Chicago Internal Medicine Practice and Research and medical director to 3 skilled nursing facilities in Illinois. Before the arrival of Drizalma Sprinkle™, he would need to resort to prescribing a different medication for those unable to take traditional pills.

"I'm a firm believer in duloxetine and the medication itself, especially as a non-opiod option for appropriate patients," Mahajan says. "This formulation just adds to the benefits by opening it up to another group of patients who weren't eligible before because they couldn't swallow pills."

Crushing pills can introduce variables into the medication delivery process.

Rajput, too, avoids grinding or crushing pills whenever possible, noting that it is difficult to tell how much of a drug may be lost in the mortar-and-pestle — and that using and cleaning the crushing device between each drug and each patient adds a lot of time in a facility with dozens of patients and 2 or 3 daily med passes.

A 4-IN-1 APPROACH REDUCES POLYPHARMACY

Accurate diagnosis of mental health and swallowing disorders are key components of the Centers for Medicare & Medicaid Services' Patient-Driven Payment Model. Over the last several

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS (cont'd)
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 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 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 $HbA1^c$ have been observed.

ADVERSE REACTIONS

The most common adverse reactions (≥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

Please see additional Important Safety Information throughout.

years, the agency also has put a premium on reducing the number of medications prescribed to residents.

Drizalma Sprinkle™ treats both major depressive disorder (MDD) and generalized anxiety disorder (GAD), making it an ideal 2-in-1 solution. But Drizalma Sprinkle™ goes further: It is also indicated for diabetic peripheral neuropathic pain and chronic musculoskeletal pain.

"In one formulation, you can treat four conditions that are very common among seniors," Rajput says. "We know this is an effective way to treat GAD and MDD, and we want to prioritize that treatment. It also helps with Diabetic Peripheral Neuropathic Pain (DPNP) in adults and Chronic Musculoskeletal Pain, which may contribute to MDD."

"A sprinkle formulation is a win-win for everyone really."

— Manzar Rajput, MD, Great Lakes Psychiatric Associates

SSRIs and SNRIs, including duloxetine, have been associated with cases of clinically significant hyponatremia in elderly patients, who may be at greater risk for this adverse event.

Recognizing the importance of Drizalma Sprinkle™, the top 10 Medicare Part D plans are covering the drug, making it an affordable option for 91% of eligible US lives and providers who want to use it. ■

To learn more, visit https://drizalmasprinkle.com/

4 INDICATIONS, 1 CAPSULE

Drizalma Sprinkle™is available in 20 mg, 30 mg, 40 mg and 60 mg dosage strengths and is indicated for the treatment of:

- **Major depressive disorder in adults**
- **Generalized anxiety disorder in adults and pediatric patients 7 to 17 years old**
- **Diabetic peripheral neuropathic pain in adults**
- **Chronic musculoskeletal pain in adults**

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS

applesauce; or administered via nasogastric tube.

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. Advise patients that Drizalma Sprinkle™ use during the month before delivery may lead to an increased risk for postpartum hemorrhage and may increase the risk of neonatal complications requiring prolonged hospitalization, respiratory support, and tube feeding.

Lactation: Advise breastfeeding women using duloxetine to monitor infants for sedation, poor feeding, and poor weight gain and to seek medical care if they notice these signs.

To report SUSPECTED ADVERSE REACTIONS, contact Sun Pharmaceutical Industries, Inc. at 1-800-818-4555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Brief Summary of Full Prescribing Information, including Boxed Warning, on next page.

Brief Summary of Prescribing Information for Drizalma Sprinkle™ (duloxetine delayed-release capsules). This Brief Summary does not include all the information needed to use Drizalma Sprinkle™ safely and effectively. See full Prescribing Information for Drizalma Sprinkle™.

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

See full prescribing information for complete boxed warning.

Increased risk of suicidal thinking and behavior in pediatric and young adult patients taking antidepressants.

Closely monitor all antidepressant-treated patients for clinical worsening and for emergence of suicidal thoughts and behaviors.

INDICATIONS AND USAGE

Drizalma Sprinkle™ (duloxetine delayed-release capsules) is a serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for:

- Major Depressive Disorder (MDD) in adults
- Generalized Anxiety Disorder (GAD) in adults and pediatric patients aged 7 to 17 years old
- Diabetic Peripheral Neuropathic Pain (DPNP) in adults
- Chronic Musculoskeletal Pain in adults

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.

DOSAGE AND ADMINISTRATION

- Drizalma Sprinkle™ can 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
- Missed doses should be taken as soon as it is remembered. Patients should not take two doses of Drizalma Sprinkle™ at the same time
- There is no evidence that doses greater than 60 mg/day confers additional benefit, while some adverse reactions were observed to be dose-dependent

WARNINGS AND PRECAUTIONS

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- **Orthostatic Hypotension, Falls, and Syncope:** Cases have been reported with duloxetine delayed- release capsules therapy
- **Serotonin Syndrome:** Increased risk when coadministered with other serotonergic agents (eg, SSRI, SNRI, triptans), but also when taken alone. If it occurs, discontinue Drizalma Sprinkle™ and initiate supportive treatment
- **Increased Risk of Bleeding:** Duloxetine may increase the risk of bleeding events. A post-marketing study showed a higher incidence of postpartum hemorrhage in mothers taking duloxetine. 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:** Taper dose when possible and monitor for discontinuation symptoms
- **Activation of Mania or Hypomania:** Use cautiously in patients with bipolar disorder. Cautions patients about the risk of activation of mania/hypomania
- **Angle-Closure Glaucoma:** Avoid use of antidepressants, including Drizalma Sprinkle™, in patients with untreated anatomically narrow angles
- **Seizures:** Prescribe 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 HbA_{1c} have been observed

ADVERSE REACTIONS

Most common adverse reactions (≥5% and at least twice the incidence of placebo patients) nausea, dry mouth, somnolence, constipation, decreased appetite, and hyperhidrosis.

DRUG INTERACTIONS

- Potent CYP1A2 Inhibitors: Avoid concomitant use
- CYP2D6 Substrates: Consider dose reduction with concomitant use

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:** Third trimester use may increase risk of symptoms of poor adaptation (respiratory distress, temperature instability, feeding difficulty, hypotonia, tremor, irritability) in the neonate. Advise patients that Drizalma Sprinkle™ use during the month before delivery may lead to an increased risk for postpartum hemorrhage and may increase the risk of neonatal complications requiring prolonged hospitalization, respiratory support and tube feeding.
- **Lactation:** Advise breastfeeding women using duloxetine to monitor infants for sedation, poor feeding and poor weight gain and to seek medical care if they notice these signs.

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Please read full Prescribing Information and Medication Guide for Drizalma Sprinkle™ and discuss any questions with your doctor.

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