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Press Releases >

June 21, 2018

NOCDURNA® (desmopressin acetate) Now Approved by U.S. FDA as First Sublingual Tablet to Treat Nocturia due to Nocturnal Polyuria

Clinical trials demonstrated an average reduction of nighttime voids of 52% in women and 43% in men relative to mean baseline (reduction of 1.5 and 1.3 voids respectively)[1]

NOCDURNA sublingual tablets dissolve rapidly and have specific dosing designed for men and women to deliver a low and effective dose of desmopressin[1]

Safety and efficacy of NOCDURNA has been demonstrated in long-term clinical trials of up to 3 years[1]

Parsippany, NJ – June 21, 2018 – The U.S. Food and Drug Administration (FDA) granted Ferring Pharmaceuticals Inc. approval to market NOCDURNA®, the first sublingual tablet for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. The formulation of the sublingual tablet and sex-specific dosing was demonstrated to be effective in reducing nighttime trips to the bathroom in adults 18 years and older.[1]

Nocturnal polyuria, a disease of the kidneys, is the most common underlying cause of nocturia, which can affect adults at every age. It occurs when a person has insufficient nocturnal vasopressin, causing an overproduction of urine in the kidneys at night.[2] Unlike treatments that target the bladder or prostate, NOCDURNA acts on receptors in the kidney to absorb more fluid and produce less urine during the night while patients sleep. NOCDURNA was approved with a boxed warning because it can cause hyponatremia.[1]

"Millions of individuals across the country face nocturia each night, many of whom suffer the daytime consequences of fatigue and lost productivity," stated Jeffrey P. Weiss, MD, FACS, Professor and Chairman of Urology, State University of New York (SUNY) Downstate Medical Center. "NOCDURNA offers the first sublingual tablet that can target the source of nighttime urination, the kidney, and effectively reduce the number of times patients have to wake up each night to urinate."

"For more than a decade, Ferring has provided innovative treatments for patients suffering from nocturia in many other countries around the world," said Paul Navarre, CEO, Ferring US. "Following today's FDA approval, we are delighted to make NOCDURNA available as an option for US healthcare providers and their patients."

The FDA approval of NOCDURNA is based on three double-blind placebo-controlled, multi-center, randomized trials and one open-label extension trial of up to three years in patients 18 years and older. Included in the clinical trials were patients also taking OAB or BPH medications. The co-primary endpoints in studies 1 and 2 were the change in number of nighttime voids

compared to baseline, and the percentage of patients who achieved at least a 33% reduction from baseline in the mean number of nighttime voids during three months of treatment. Clinical trials demonstrated an average reduction of nocturnal voids of 52% in women (n=118) and 43% in men (n=102) relative to mean baseline (reduction of 1.5 and 1.3 voids respectively). The mean baseline was 2.9 for women and 3.0 for men. Also, 78% of women and 67% of men receiving NOCDURNA achieved a 33% reduction in mean number of nocturnal voids over a three month period compared to baseline.[1]

NOCDURNA can cause hyponatremia. Severe hyponatremia can be life-threatening, leading to seizures, coma, respiratory arrest, or death. NOCDURNA is contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake, illnesses that can cause fluid or electrolyte imbalances, and in those using loop diuretics or systemic or inhaled glucocorticoids. Ensure the serum sodium concentration is normal before starting or resuming NOCDURNA. Measure serum sodium within 7 days and approximately 1 month after initiating therapy, and periodically during treatment. Monitor serum sodium levels more frequently in patients 65 years of age and older and in patients at increased risk of hyponatremia. If hyponatremia occurs, NOCDURNA may need to be temporarily or permanently discontinued.[1]

NOCDURNA will be available by prescription for patients everywhere in the United States in the second half of 2018.

About NOCDURNA

NOCDURNA is the first and only sublingual tablet indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void.

About Nocturia due to Nocturnal Polyuria

Nocturia is the need to awaken at night to urinate. It is a condition that affects more than 70 million people in the United States.[3] Many urologic and non-urologic factors can cause nocturia, but the most common underlying cause is nocturnal polyuria, a disease of the kidneys.[2] Nocturnal polyuria is present in up to 88% of nocturia patients. It occurs when a person's kidneys produce too much urine at night, causing the need to wake two or more times to urinate. Nocturnal polyuria can exist alone, or it can be commonly found in patients with overactive bladder (OAB) or benign prostatic hyperplasia (BPH).[4]

About Ferring Pharmaceuticals

Ferring Pharmaceuticals is a research-driven biopharmaceutical company devoted to identifying, developing and marketing innovative products in the fields of reproductive health, women's health, urology, gastroenterology, endocrinology and orthopaedics. For more information, call 1-888-FERRING (1-888-337-7464); visit www.FerringUSA.com.

Visit www.nocdurna.com for full prescribing information including Boxed WARNING and Medication Guide.

INDICATION

NOCDURNA is a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: HYPONATREMIA

See full Prescribing Information for complete boxed warning

· **NOCDURNA can cause hyponatremia, which may be life-threatening if severe.**

· **NOCDURNA is contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake, illnesses that can cause fluid or electrolyte imbalances, and in those using loop diuretics or systemic or inhaled glucocorticoids.**

· **Ensure serum sodium concentration is normal before starting or resuming NOCDURNA. Measure serum sodium within 1 week and approximately 1 month after initiating therapy and periodically during treatment. More frequently monitor serum sodium in patients 65 years of age and older and in patients at increased risk of hyponatremia.**

· **If hyponatremia occurs, NOCDURNA may need to be temporarily or permanently discontinued.**

CONTRAINDICATIONS

Hyponatremia or a history of hyponatremia

Polydipsia

Concomitant use with loop diuretics or systemic or inhaled glucocorticoids

Estimated glomerular filtration rate below 50 mL/min/1.73 m^2

Syndrome of inappropriate antidiuretic hormone secretion (SIADH)

During illnesses that can cause fluid or electrolyte imbalance

Heart failure

Uncontrolled hypertension

WARNINGS AND PRECAUTIONS

Limit fluid intake to a minimum from 1 hour before until 8 hours after administration. Treatment without concomitant reduction of fluid intake may lead to fluid retention and hyponatremia.

Fluid retention: Not recommended in patients at risk of increased intracranial pressure or history of urinary retention.

ADVERSE REACTIONS

Common adverse reactions (>2% incidence) included dry mouth, hyponatremia or blood sodium decreased, and dizziness.

DRUG INTERACTIONS

Monitor serum sodium more frequently when NOCDURNA is concomitantly used with drugs that may increase the risk of hyponatremia (e.g. tricyclic antidepressants, selective serotonin re-uptake inhibitors, chlorpromazine, opiate analgesics, thiazide diuretics, carbamazepine, lamotrigine, sulfonylureas, particularly chlorpropamide and NSAIDS).

USE IN SPECIFIC POPULATIONS

Pregnancy: Use of NOCDURNA is not recommended.

Geriatric Use: Increased risk of hyponatremia if 65 years of age or older. Monitor serum sodium more frequently.

To report SUSPECTED ADVERSE REACTIONS, contact Ferring at 1-888-337-7464 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information, including Boxed WARNING, and Medication Guide.

References:

1. NOCDURNA [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc. 2. Van Kerrebroeck P et al. Terminology, Epidemiology, Etiology, and Pathophysiology of Nocturia. Neurol and Urodynamics. 2014;33:S2-S5. 3. Vaughan CP et al. Differences in the association of nocturia and functional outcomes of sleep by age and gender: a cross-sectional, population-based study. Clin Ther. 2016;38(11):2386-2393. 4. Weiss JP et al. The evaluation and treatment of nocturia: a consensus statement. BJU Int. 2011;108(1):6-21.

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For more information, please contact