

Nocdurna[®] (desmopressin acetate) – New drug approval

- On June 21, 2018, the [FDA announced](#) the approval of [Ferring's Nocdurna \(desmopressin acetate\)](#) sublingual tablets for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.
 - In the Nocdurna clinical trials nocturnal polyuria was defined as night-time urine production exceeding one-third of the 24-hour urine production.
 - Before starting Nocdurna, evaluate the patient for possible causes for the nocturia, including excessive fluid intake prior to bedtime, and address other treatable causes of nocturia; and confirm the diagnosis of nocturnal polyuria with a 24-hour urine collection, if one has not been obtained previously.
- Nocturia affects more than 70 million Americans. The most common underlying cause is nocturnal polyuria, a disease of the kidneys present in up to 88% of nocturia patients. It occurs when a person has insufficient nocturnal vasopressin, resulting in an overproduction of urine in the kidneys at night.
- Nocdurna contains desmopressin, an antidiuretic mediated by stimulation of vasopressin 2 receptors, thereby increasing water re-absorption in the kidneys and reducing urine production.
 - Desmopressin is also generically available as an [oral tablet](#) and [nasal spray](#) for diabetes insipidus. The oral tablet is also approved for primary nocturnal enuresis.
 - Desmopressin is also generically available as an [injection](#) for use in patients with hemophilia A, von Willebrand's disease, and diabetes insipidus; and a branded nasal spray ([Noctiva[™]](#)) for nocturnal polyuria.
- The efficacy of Nocdurna was established in two 3-month placebo-controlled trials involving adults with nocturia due to nocturnal polyuria. Study 1 enrolled only women and study 2 enrolled only men. The co-primary endpoints in both trials were change in number of nocturia episodes per night from baseline and 33% responder status during 3-months of treatment, defined as $\geq 33\%$ decrease in the mean number of nocturnal voids from baseline.
 - The mean change in nocturia episodes from baseline was greater with Nocdurna vs. placebo (difference: women = -0.3 [95% CI: -0.5, -0.1]; men = -0.4 [95% CI: -0.6, -0.2]).
 - The 33% responder rate was also greater with Nocdurna vs. placebo (women: 78% vs. 62%, respectively; men: 67% vs. 50%, respectively).
 - The efficacy and safety of Nocdurna have not been established for the treatment of all causes of nocturia.
- Nocdurna carries a boxed warning for hyponatremia.
- Nocdurna is contraindicated in:
 - Patients with the following conditions due to an increased risk of hyponatremia: hyponatremia or a history of hyponatremia; polydipsia; concomitant use with loop diuretics or systemic or inhaled corticosteroids; renal impairment with estimated glomerular filtration rate < 50 mL/min/1.73 m²; known or suspected syndrome of inappropriate antidiuretic hormone secretion; during illness that can cause fluid or electrolyte imbalance, such as gastroenteritis, salt-wasting nephropathies, or systemic infection.
 - Patients with the following conditions because fluid retention increases the risk of worsening the underlying condition: heart failure or uncontrolled hypertension.

- Other warnings and precautions of Nocdurna include fluid retention.
- The most common adverse reactions (> 2%) with desmopressin use include dry mouth, hyponatremia, and dizziness.
- The recommended dose of Nocdurna is 27.7 mcg for women or 55.3 mcg for men once daily, administered sublingually (SL) 1 hour before bedtime without water.
 - Before starting or resuming Nocdurna, the patient's sodium concentration should be assessed. Nocdurna should only be started or resumed in patients with normal serum sodium concentration.
 - The patient's serum sodium concentration should be checked within the 1st week and again 1 month after initiating or resuming therapy. More frequent monitoring is recommended for patients ≥ 65 years of age and those at risk of hyponatremia.
 - Patients should be instructed to empty their bladder immediately before bedtime and limit fluid intake to a minimum from 1 hour before until 8 hours after administration.
- Ferring plans to launch Nocdurna in the second half of 2018. Nocdurna will be available as 27.7 mcg and 55.3 mcg SL tablets, equivalent to 25 mcg and 50 mcg of desmopressin, respectively.



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