Noctiva™ (desmopressin acetate) – New drug approval

- On March 3, 2017, the FDA announced the approval of Serenity Pharmaceutical's Noctiva (desmopressin acetate), for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.
    - Nocturnal polyuria was defined in the Noctiva clinical trials as night-time urine production exceeding one-third of the 24-hour urine production.
    - Before starting Noctiva, evaluate the patient for possible causes for the nocturia, including excessive fluid intake prior to bedtime, and optimize the treatment of underlying conditions that may be contributing to the nocturia. Confirm the diagnosis of nocturnal polyuria with a 24-hour urine collection, if one has not been obtained previously.
    - Noctiva has not been studied in patients < 50 years of age.
- Waking up at night to urinate (nocturia) is a symptom that can be caused by a variety of conditions, such as congestive heart failure, poorly controlled diabetes, medications, or diseases of the bladder or prostate.
- The safety and efficacy of Noctiva were based on two placebo-controlled trials involving 1,045 patients ≥ 50 years old with nocturia due to nocturnal polyuria.
    - More patients in the Noctiva group achieved at least a 50% reduction in nocturic episodes per night from baseline vs. placebo (trial 1: 35% - 47% vs. 27%; trial 2: 41% - 49% vs. 29%).
    - In addition, patients treated with Noctiva had more nights with one or fewer night-time urinations.
- Noctiva carries a boxed warning for hyponatremia.
- Noctiva is contraindicated in patients with the following conditions due to an increased risk of severe hyponatremia: hyponatremia or a history of hyponatremia, polydipsia, primary nocturnal enuresis, concomitant use with loop diuretics, concomitant use with systemic or inhaled glucocorticoids, renal impairment with an estimated glomerular filtration rate below 50 mL/min/1.73 m^2, known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion, and during illnesses that can cause fluid or electrolyte imbalance, such as gastroenteritis, salt-wasting nephropathies, or systemic infection.
- Noctiva is also contraindicated in patients with the following conditions because fluid retention increases the risk of worsening the underlying condition: congestive heart failure (New York Heart Association Class II to IV) and uncontrolled hypertension.
- Other warnings and precautions of Noctiva include concurrent nasal conditions.
- The most common adverse reactions (> 2%) with Noctiva use were nasal discomfort, nasopharyngitis, nasal congestion, sneezing, hypertension/increased blood pressure, back pain, epistaxis, bronchitis, and dizziness.
- The recommended dose of Noctiva is as follows:
    - For patients < 65 years old who are not at increased risk for hyponatremia: 1 spray of 1.66 mcg in either nostril nightly approximately 30 minutes before going to bed.

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  - For patients ≥ 65 years old or younger patients at risk for hyponatremia: 0.83 mcg nightly, which may be increased to 1 spray of 1.66 mcg after at least 7 days, if needed, provided the serum sodium has remained normal.
  - Noctiva should be primed with 5 actuations before initial use. Re-prime with 2 actuations if not used for more than 3 days.

- Serenity's launch plans for Noctiva are pending. Noctiva will be available as a preservative-free nasal spray delivering 0.83 mcg of desmopressin acetate (equivalent to 0.75 mcg desmopressin) or 1.66 mcg of desmopressin acetate (equivalent to 1.5 mcg desmopressin) in each spray (0.1 mL).