

**NOCDURNA (desmopressin acetate) sublingual tablets,
NOCTIVA (desmopressin acetate) nasal spray****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Nocdurna (desmopressin acetate) and Noctiva (desmopressin acetate) are vasopressin analogs. The antidiuretic effects of desmopressin are mediated by stimulation of vasopressin 2 (V2) receptors, thereby increasing water re-absorption in the kidneys, and reducing urine production (1-2).

Regulatory Status

FDA-approved indication: Nocdurna and Noctiva are vasopressin analogs indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void (1-2).

Nocdurna and Noctiva have boxed warnings that they can cause hyponatremia, which may be life-threatening if severe. Nocdurna and Noctiva are 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. Serum sodium concentration should be normal before starting or resuming Nocdurna or Noctiva and should be measured within 1 week and 1 month after initiating therapy and then periodically during treatment. If hyponatremia occurs, Nocdurna or Noctiva may need to be temporarily or permanently discontinued (1-2).

Nocdurna and Noctiva are contraindicated in: hyponatremia or history of hyponatremia, polydipsia, primary nocturnal enuresis, concomitant use with loop diuretics or systemic or inhaled glucocorticoids, estimated glomerular filtration rate below 50 mL/min/1.73 m², syndrome of inappropriate antidiuretic hormone secretion (SIADH), during illnesses that can cause fluid or electrolyte imbalance, heart failure, and uncontrolled hypertension (1-2).

Nocdurna and Noctiva can cause fluid retention. They are not recommended in patients at risk of increased intracranial pressure or history of urinary retention. Fluid intake should be limited to a minimum from 1 hour before until 8 hours after administration of desmopressin (1-2).



Federal Employee Program.

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The safety and effectiveness of Nocdurna and Noctiva in pediatric patients have not been established (1).

Summary

Nocdurna (desmopressin acetate) and Noctiva (desmopressin acetate) are vasopressin analogs. The antidiuretic effects of desmopressin are mediated by stimulation of vasopressin 2 (V2) receptors, thereby increasing water re-absorption in the kidneys, and reducing urine production. The safety and effectiveness of Nocdurna and Noctiva in pediatric patients have not been established (1-2).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Nocdurna and Noctiva while maintaining optimal therapeutic outcomes.

References

1. Nocdurna [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; November 2020.
2. Noctiva [package insert]. Chesterfield, MO. Avadel Specialty Pharmaceuticals, LLC; December 2017.