Noctiva (desmopressin acetate)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Noctiva
- **Generic name:** Desmopressin acetate
- **Pharmacological class:** Vasopressin (synthetic)
- **Strength and Formulation:** 0.83mcg, 1.66mcg; per nasal spray; preservative-free
- **Manufacturer:** Avadel Pharmaceuticals
- **How supplied:** Nasal spray—3.5mL (30 sprays)
- **Legal Classification:** Rx

NOCTIVA


Rx Only
NDC 71758-106-55
Noctiva™
(desmopressin acetate) Nasal Spray
0.83 mcg / 0.1 mL
*each spray contains 0.1 mL
Net Content 3.8g or 30 doses
FOR INTRANASAL USE ON
Avadel®
Rx Only
NDC 71758-107-55
Noctiva™
(desmopressin acetate) Nasal Spray
1.66 mcg / 0.1 mL
*each spray contains 0.1 mL
Net Content 3.8g or 30 doses
FOR INTRANASAL USE ONI
Avadel®

Indications

- Nocturia due to nocturnal polyuria in adults who awaken ≥2 times per night to void

- **Limitations of use:** Not studied in patients <50yrs of age

Dosage & Administration

- **<65yrs** (without increased risk of hyponatremia): 1 spray (1.66mcg) in either nostril approx. 30mins before bedtime

Dosage & Administration

- **≥65yrs** (or <65yrs with increased risk of hyponatremia): initially 1 spray (0.83mcg) in either nostril approx. 30mins before bedtime; may increase to 1.66mcg after ≥7 days, if needed, provided the serum sodium has remained normal

Considerations for Special Populations

- **Pediatric:** Not established
- **Pregnancy:** Not recommended
- **Nursing mothers:** Consider benefits of breastfeeding along with mother's need and potential adverse effects
- **Elderly:** Higher incidence of hyponatremia
- **Renal impairment:** See Contraindications
- **Hepatic impairment:** Not studied

Contraindications

- Hyponatremia, or history of
- Polydipsia
- Primary nocturnal enuresis
- Concomitant loop diuretics, systemic or inhaled glucocorticoids
- Renal impairment (eGFR <50mL/min/1.73m^2)
- Known or suspected SIADH secretion

Contraindications

- During illnesses that can cause fluid/electrolyte imbalance (eg, gastroenteritis, salt-wasting nephropathies, or systemic infection)
- CHF (NYHA Class II–IV)
- Uncontrolled hypertension

Warnings/Precautions

- Evaluate and confirm diagnosis with 24-hr urine collection prior to initiation
- Risk of hyponatremia (may be severe)
- Monitor serum sodium levels prior to initiating or resuming dose, within 7 days and approx. 1 month after starting or increasing dose, and periodically thereafter

Warnings/Precautions

- Monitor more frequently for elderly (≥65yrs) or those on concomitant drugs that can increase the risk of hyponatremia
- **Interrupt or permanently discontinue** if hyponatremia occurs; treat appropriately
- CHF (NYHA Class I): monitor volume status

Warnings/Precautions

- Risk of increased intracranial pressure, history of urinary retention**: not recommended**
- **Discontinue** if concurrent nasal conditions (eg, nasal mucosa atrophy, acute/chronic rhinitis) that may increase absorption, until resolved

Interactions

- **See Contraindications**
- May start or resume Noctiva 3 days or 5 half-lives after glucocorticoid is discontinued (whichever is longer)
- Concomitant other **intranasal drugs**: not recommended

Interactions

- Concomitant medications that may cause **water retention** or increase **hyponatremia** risk (eg, tricyclics, SSRIs, NSAIDs, opioids, chlorpromazine, carbamazepine, lamotrigine, thiazides): monitor serum sodium more frequently

Adverse Reactions

- Nasal discomfort
- Nasopharyngitis
- Nasal congestion
- Sneezing
- Hypertension/BP increased
- Back pain
- Epistaxis
- Bronchitis
- Dizziness
- Hyponatremia
- Fluid retention

Mechanism of Action

- Desmopressin is a synthetic analog of vasopressin
- It is a selective agonist at V2 receptors on renal cells in the collecting ducts, increasing water re-absorption in the kidneys, and reducing urine production

Clinical Studies

- Noctiva was evaluated in two 12-week, randomized, double-blind, placebo-controlled, multicenter trials in adults aged 50 years and older

Clinical Studies

- **Trial 1** (N=612) and **Trial 2** (N=433) randomized patients to Noctiva 1.66mcg, Noctiva 0.83mcg or placebo
- **Nocturnal polyuria** was defined as a nighttime urine production exceeding 1/3 of the 24-hour urine production confirmed with a 24-hour urine frequency/volume chart

Clinical Studies

- The **co-primary efficacy endpoints** were:
  - Change in mean number of nocturic episodes per night from baseline during the 12-week treatment period
  - Percentage of patients who achieved ≥50% reduction from baseline in the mean number of nocturic episodes per night during the treatment period

Clinical Studies

- In **Trial 1**, the change in mean number of nocturic episodes per night from baseline was:
  - **Noctiva 1.66mcg:** -1.5
  - **Noctiva 0.83mcg:** -1.5
  - **Placebo:** -1.2
- 47% of Noctiva 1.66mcg patients and 35% of Noctiva 0.83mcg patients achieved ≥50% reduction in nocturic episodes vs 27% of placebo patients

Clinical Studies

- In **Trial 2**, the change in mean number of nocturic episodes per night from baseline was:
  - **Noctiva 1.66mcg:** -1.5
  - **Noctiva 0.83mcg:** -1.4
  - **Placebo:** -1.1
- 49% of Noctiva 1.66mcg patients and 41% of Noctiva 0.83mcg patients achieved ≥50% reduction in nocturic episodes vs 29% of placebo patients

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/noctiva/drug/34816/