Nocdurna

(desmopressin acetate)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Nocdurna
- **Generic name:** Desmopressin acetate
- **Pharmacological class:** Vasopressin (synthetic)
- **Strength and Formulation:** 27.7mcg, 55.3mcg; sublingual tablets
- **Manufacturer:** Ferring Pharmaceuticals
- **How supplied:** Sublingual tablets—30
- **Legal Classification:** Rx

Nocdurna


30 Sublingual Tablets (3 x 10 count blister cards)
Rx ONLY
NDC 55566-5070-1
Nocdurna®
(desmopressin acetate) Sublingua
55.3 mcg per tablet
ATTENTION PHARMACIST: Each patient is required to receive the enclosed M
Do not break open and dispense partial quantities.
30 Sublingual Tablets (3 x 10 count blister cards)
Rx ONLY
NDC 55566-5050-1
Nocdurna®
(desmopressin acetate) Sublingual Tablets
27.7 mcg per tablet
ATTENTION PHARMACIST: Each patient is required to receive the enclosed Medication Guide.
Do not break open and dispense partial quantities.
FERRING
PHARMACEUTICALS

Indication

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

Dosage & Administration

- Empty bladder immediately before bedtime
- Limit fluid intake to a minimum from 1hr before until 8hrs after dose
- Dissolve under tongue
- **Females**: 27.7mcg once daily 1hr before bedtime
- **Males**: 55.3mcg once daily 1hr before bedtime

Considerations for Special Populations

- **Pregnancy:** Not recommended
- **Nursing mothers:** Desmopressin is present in small amounts in human milk; consider risks and benefits
- **Pediatric:** Not established
- **Geriatric:** Increased risk of hyponatremia in patients ≥65yrs
- **Renal impairment:** Contraindicated in patients with eGFR <50mL/min/1.73m^2

Contraindications

- Hyponatremia, or history of
- Polydipsia
- Concomitant loop diuretics, systemic or inhaled glucocorticoids
- 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)
- Heart failure
- Uncontrolled hypertension

Boxed Warning

- May cause **hyponatremia**, which may be life-threatening if severe
- If hyponatremia occurs, Nocdurna may need to be temporarily or permanently discontinued

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 therapy, 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
- Risk of increased **intracranial pressure**, history of **urinary retention**: not recommended

Interactions

- See Contraindications
- Avoid **caffeine** or **alcohol** before bedtime
- May start or resume Nocdurna 3 days or 5 half-lives after **glucocorticoid** is discontinued (whichever is longer)
- Concomitant medications that may cause **water retention** or increase **hyponatremia** risk (eg, tricyclics, SSRIs, NSAIDs, opioids, chlorpromazine, carbamazepine, lamotrigine, thiazides, chlorpropamide): monitor serum sodium more frequently

Adverse Reactions

- Dry mouth
- Hyponatremia
- Dizziness
- Headache

Mechanism of Action

- 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

Clinical Studies

- The efficacy of Nocdurna was established in two 3-month trials; **Study 1** enrolled only women while **Study 2** enrolled only men

Clinical Studies

- In **Study 1**, women (N=237) were randomized to receive either Nocdurna 27.7mcg or placebo every night approximately 1 hour before bedtime; men (N=230) in **Study 2** received either Nocdurna 55.3mcg or placebo

Clinical Studies

- The **co-primary endpoints** in both trials were: 1) change in number of nocturia episodes/night from baseline during the 3-month period and; 2) 33% responder status during 3 months of treatment (a decrease of 33% in the mean number of nocturnal voids compared to baseline)

Clinical Studies

- Results showed an average reduction of nocturnal voids from baseline of **-1.5** (difference from placebo -0.3) for women and **-1.3** for men (difference from placebo -0.4) with Nocdurna
- In addition, 78% of women and 67% of men in the Nocdurna groups achieved 33% responder status vs 62% and 50% for placebo, respectively

Clinical Studies

- Percentage of nights with **no nocturnal voids**
  - Study 1 (women): 19% for Nocdurna vs 15% for placebo
  - Study 2 (men): 15% for Nocdurna vs 7% for placebo
- Percentage of nights with **at most 1 nocturnal void**
  - Study 1: 58% for Nocdurna vs 45% for placebo
  - Study 2: 44% for Nocdurna vs 32% for placebo

New Product Monograph

- For more information view the product monograph available at:

www.empr.com/nocdurna/drug/34868/