Nocdurna®
(desmopressin acetate) Sublingual Tablets

DOSAGE, ADMINISTRATION, and SODIUM MONITORING

DOSAGE & ADMINISTRATION

Clinical studies demonstrated that NOCDURNA was effective at treating nocturia due to nocturnal polyuria at these doses, specially designed for men and women.[1]

Take 1 tablet daily, 1 hour before bedtime, without water

MEN
55.3 mcg/day

WOMEN
27.7 mcg/day

Packaging is not actual size.

WHEN TAKING NOCDURNA

Keep under tongue until fully dissolved[1]	Limit fluids, starting from 1 hour before taking NOCDURNA and for 8 hours after taking it[1]	Avoid caffeine or alcohol before bedtime[1]	Empty bladder immediately before bedtime[1]

INDICATION

NOCDURNA is a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: HYPONATREMIA

See full Prescribing Information for complete boxed warning

- **NOCDURNA can cause hyponatremia, which may be life-threatening if severe.**
- **NOCDURNA is 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.**
- **Ensure serum sodium concentration is normal before starting or resuming NOCDURNA. Measure serum sodium within 1 week and approximately 1 month after initiating therapy and periodically during treatment. More frequently monitor serum sodium in patients 65 years of age and older and in patients at increased risk of hyponatremia.**
- **If hyponatremia occurs, NOCDURNA may need to be temporarily or permanently discontinued.**

Please see additional Important Safety Information on reverse and full Prescribing Information, including boxed warning and medication guide, attached.

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DOSAGE, ADMINISTRATION, and SODIUM MONITORING

SERUM SODIUM MONITORING

NOCDURNA has a Boxed Warning for and is contraindicated in patients with hyponatremia or a history of hyponatremia.

CHECK SODIUM LEVELS AT THESE TIMEPOINTS[1]

BEFORE
STARTING OR RESUMING THERAPY

1 WEEK
WITHIN 1 WEEK OF STARTING OR RESUMING THERAPY

1 MONTH
AT 1 MONTH OF STARTING OR RESUMING THERAPY

PERIODICALLY
AS CLINICALLY APPROPRIATE*

*Patients 65 and older and those at increased risk for hyponatremia should be monitored more frequently.[1]

NOCDURNA may need to be temporarily or permanently discontinued if the patient develops hyponatremia, and treatment for hyponatremia instituted, depending on the clinical circumstances, including the duration and severity of the hyponatremia.[1]

IMPORTANT SAFETY INFORMATION (cont)

CONTRAINDICATIONS

- Hyponatremia or a history of hyponatremia
- Polydipsia
- Concomitant use with loop diuretics or systemic or inhaled glucocorticoids
- Estimated glomerular filtration rate below 50 mL/min/1.73 m^2
- Syndrome of inappropriate antidiuretic hormone secretion (SIADH)
- During illnesses that can cause fluid or electrolyte imbalance
- Heart failure
- Uncontrolled hypertension

WARNINGS AND PRECAUTIONS

- Limit fluid intake to a minimum from 1 hour before until 8 hours after administration. Treatment without concomitant reduction of fluid intake may lead to fluid retention and hyponatremia.
- Fluid retention: Not recommended in patients at risk of increased intracranial pressure or history of urinary retention.

ADVERSE REACTIONS

Common adverse reactions (>2% incidence) included dry mouth, hyponatremia or blood sodium decreased, and dizziness.

DRUG INTERACTIONS

Monitor serum sodium more frequently when NOCDURNA is concomitantly used with drugs that may increase the risk of hyponatremia (e.g. tricyclic antidepressants, selective serotonin re-uptake inhibitors, chlorpromazine, opiate analgesics, thiazide diuretics, carbamazepine, lamotrigine, sulfonylureas, particularly chlorpropamide and NSAIDS).

USE IN SPECIFIC POPULATIONS

Pregnancy: Use of NOCDURNA is not recommended.

Geriatric Use: Increased risk of hyponatremia if 65 years of age or older. Monitor serum sodium more frequently.

To report SUSPECTED ADVERSE REACTIONS, contact Ferring at 1-888-337-7464 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information, including boxed warning and medication guide, attached.

Reference: 1. NOCDURNA [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.

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