NOCDURNA®

HOW DOES NOCDURNA® (DESMOPRESSIN) WORK?

Desmopressin is a synthetic analogue of the antidiuretic hormone vasopressin, which increases reabsorption of water, concentrates urine and decreases nocturnal urine production[1,3]

Desmopressin exerts its antidiuretic action by specifically binding to V2 receptors (avoiding undesirable vasopressor effects)[1,2]

Nocdurna® desmopressin

NOCDURNA® is a desmopressin oral lyophilisate with a fast release and effect[3,4]

NOCDURNA® has a rapid onset of action, reaching maximum effect after a week of treatment[3,4]

Large volume of concentrated urine due to low level of AVP or lack of sensitivity of AVP

Small volume of concentrated urine

INDICATION AND GUIDELINE RECOMMENDATIONS

NOCDURNA® is currently the only medication licensed for the treatment of nocturia due to nocturnal polyuria in adults[2]

Desmopressin has the highest level of guidelines recommendation

EAU: Level 1b, Grade A[4]
ICI: Level 1, Grade A[5]
NERI: states desmopressin is beneficial for nocturia[1]

EAU: European Association of Urology;
ICI: International Consultation on Incontinence;
NERI: New England Research Institutes

NOCDURNA® DOSING

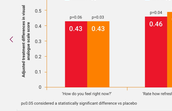
NOCDURNA® **low-dose and gender-specific desmopressin**, is indicated for all adult patients irrespective of age, with tailored dosages for MEN (50 µg* once daily) and WOMEN (25 µg* once daily)[1]

Low-dose, gender-specific dosing of NOCDURNA® was confirmed in a large clinical studies programme

In phase III clinical trials (CS25/31), doses of 10, 25, 50 and 100 µg were investigated and the recommended dose was found to be 25 µg* in women and 50–100 µg* in men[1]

Adapted from Weiss et al., 2012. A phase III, 4-week, randomized, double-blind, placebo-controlled, parallel-group, multi-center study in the United States and Canada, assessing the efficacy and safety of desmopressin in 701 patients with nocturia and a high prevalence of nocturnal polyuria.

Two confirmatory phase III trials have been conducted: CS40[6] assessed 25 µg* in women, and CS41[4] assessed 50 µg* in men



The NOCDURNA® clinical studies programme has confirmed the efficacy and safety of the approved doses of desmopressin 25 µg* for women and 50 µg* for men.

*50 µg is the approved dose in men and 25 µg is the approved dose in women

NOCDURNA® EFFICACY

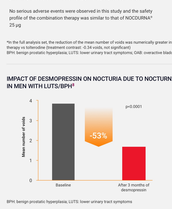
NOCDURNA® 25 µg* and 50 µg* is effective in women and men, respectively[3,4]

- **Reduces** mean number of **nocturnal voids**
- **Reduces** nocturnal **urine volume**
- **Increases time** to **first nocturnal void**
- **Prolongs** initial **sleep period**
- **Improves** nocturia-related **QoL**
- **Improves sleep quality**

*50 µg is the approved dose in men and 25 µg is the approved dose in women
QoL: quality of life

NOCDURNA® IMPROVES NOCTURIA-RELATED SLEEP QUALITY

Significant improvement of sleep quality* at month 3[3,4]



p<0.05 considered a statistically significant difference vs placebo

Adapted from Sand PK et al., 2013. A 3-month, randomized, double-blind, parallel-group study of the efficacy and safety of desmopressin vs placebo in 331 women in the United States and Canada with nocturia.
Adapted from Weiss JP et al., 2013. A 3-month, randomized, double-blind, parallel study of the efficacy and safety of oral low-dose desmopressin vs placebo in 385 men in the United States and Canada with nocturia.

NOCDURNA® increases sleep quality scores from baseline in women[3] and men[4] with nocturia due to nocturnal compared with placebo at month 3

*Patients reported on sleep quality using the sleep rating scale (1- poor to 10 -excellent).
Based on the following questions:
"How do you feel right now?", "Rate how refreshed you feel", "Rate the quality of your sleep last night"
*50 µg is the approved dose in men and 25 µg is the approved dose in women

IMPACT OF DESMOPRESSIN ON OAB AND BPH

Women with OAB/LUTS

Impact of desmopressin on nocturia due to nocturnal polyuria in women with OAB/LUTS

In a double-blind, randomized clinical trial, 49 women with OAB were exposed to a combination of NOCDURNA® (desmopressin MeA) 25 µg and tolterodine 4 mg.[7]

The combination of desmopressin and tolterodine significantly reduced the mean number of voids (**treatment contrast: -0.41 voids, p=0.049**) vs tolterodine monotherapy in the per protocol analysis*

No serious adverse events were observed in this study and the safety profile of the combination therapy was similar to that of NOCDURNA® 25 µg

Men with BPH

Impact of desmopressin on nocturia due to nocturnal polyuria in men with BPH/LUTS

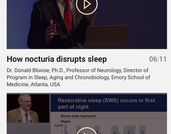
In a study of 137 men with LUTS/BPH of whom 62% were on concomitant BPH medication (α1 blockers and 5α reductase inhibitors)[8]

Desmopressin significantly reduced mean number of nocturnal voids by **53%** at month 3 (p<0.0001)

Desmopressin significantly increased the hours of uninterrupted sleep by **74%** at month 3 (p=0.0001)

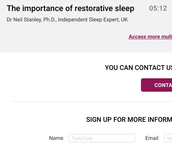
*In the full analysis set, the reduction of the mean number of voids was numerically greater in the combination therapy vs tolterodine (treatment contrast -0.34 voids, not significant).
BPH: benign prostatic hyperplasia; LUTS: lower urinary tract symptoms; OAB: overactive bladder

IMPACT OF DESMOPRESSIN ON NOCTURIA DUE TO NOCTURNAL POLYURIA IN MEN WITH LUTS/BPH[9]



BPH: benign prostatic hyperplasia; LUTS: lower urinary tract symptoms

CURRENT OAB/BPH THERAPIES DO NOT TARGET NOCTURNAL POLYURIA



BPH: benign prostate hyperplasia; OAB: overactive bladder; PDE5i: phosphodiesterase type 5 inhibitor; 5ARI: 5 alpha-reductase inhibitor

NOCDURNA® IS WELL TOLERATED IN BOTH MEN AND WOMEN

INCIDENCE OF LOW SERUM SODIUM LEVELS WITH LOW-DOSE DESMOPRESSIN COMPARED WITH PLACEBO[1,2]

Summary of Serum Sodium Levels

	Women[3]		Men[4]	
Serum sodium mmol/L	**Placebo (n=126)**	**25 µg* (n=135)**	**Placebo (n=143)**	**50 µg* (n=119)**
≤125, n (%)	0 (0%)	0 (0%)	0 (0%)	2 (2%)
126–129, n (%)	0 (0%)	3*(2%)	0 (0%)	0 (0%)
130–135, n (%)	2 (2%)	11*(8%)	2 (1%)	9 (8%)

*50 µg is the approved dose in men and 25 µg is the approved dose in women

WHAT DO THE EXPERTS SAY?

LEARN MORE

MULTIMEDIA

How nocturia disrupts sleep 06:11

Dr. Donald Bliwise, Ph.D., Professor of Neurology, Director of Program in Sleep, Aging and Chronobiology, Emory School of Medicine, Atlanta, USA

How poor sleep has an effect on your patients 05:12

Dr Neil Stanley, Ph.D., Independent Sleep Expert, UK

The importance of restorative sleep 05:12

Dr Neil Stanley, Ph.D., Independent Sleep Expert, UK

Access more multimedia resources

YOU CAN CONTACT US DIRECTLY BY EMAIL

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SIGN UP FOR MORE INFORMATION ABOUT NOCDURNA®

Name Todd Cole
Email todd_cole@gmail.com
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DOWNLOAD THE SUMMARY OF PRODUCT CHARACTERISTICS

DOWNLOAD SMPC

REFERENCES

1. Juul K et al. *Am J Physiol Renal Physiol* 2011;300:F1116–22
2. NOCDURNA EU SmPC
3. Sand PK et al. *J Urol* 2013;190:958–64
4. Weiss JP et al. *J Urol* 2013;190:965–72
5. Weiss JP et al. *BJUI Int* 2013;700–16
6. Wein AH. *J Urol* 2014;191:1052–4
7. Weiss JP et al. *Neurourol Urodyn* 2013;31:441–7
8. Bergen R et al. *World J Urol* 2014;32:1163–70
9. Kaplan SA et al. *Int Urol Nephrol* 2011;43:1119–25
10. Oelke M et al. *World J Urol* 2013;31:1341–9
11. Oelke M et al. *World J Urol* 2014;32:1127–32
12. Oelke M et al. *World J Urol* 2014;32:1149–54
13. Yamaguchi O et al. *BJUI Int* 2007;100:579–87
14. Brubaker L, Fitzgerald P. *Int Urogynecol J Pelvic Floor Dysfunct* 2007;18:737–41
15. Nitti VW et al. *BJUI Int* 2006;97:1262–6
16. Barkley R et al. *Urology* 2006;67:701–6
17. Stanley N. *Eur Urol Suppl* 2005;3:17–23
18. van Kerrebroeck P et al. *Eur Urol* 2007;52:1–9

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