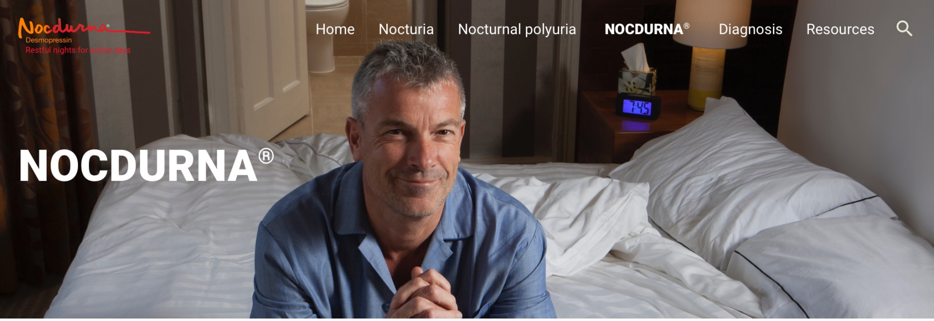
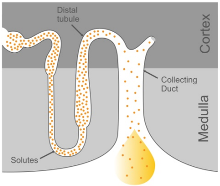


NOCDURNA®

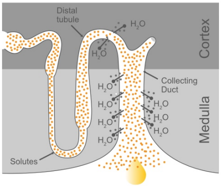
HOW DOES NOCDURNA® (DESMOPRESSIN) WORK?

Desmopressin is a synthetic analogue of the antidiuretic hormone vasopressin, which increases reabsorption of water, concentrates urine and decreases nocturnal urine production[1,2]

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



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



Small volume of concentrated urine

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]

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[5]
ICI: Level 1, Grade A[5]
NERI: states desmopressin is beneficial for nocturia[6]

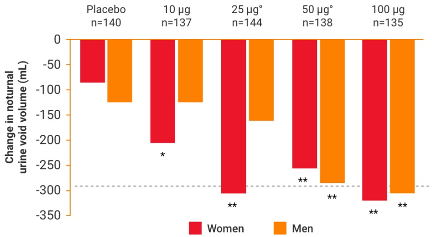
EAU: European Association of Urology;
ICI: International Consultation on Incontinence;
NERI: New England Research Institutes

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)[2]

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

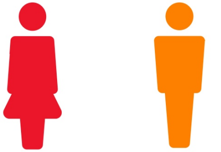
In phase III clinical trials (CS29/31), doses of 10, 25, 50 and 100 µg were investigated and the recommended dose was found to be 25 µg° in women and 50–100 µg° in men[7]



*p<0.05; **p<0.01 NOCDURNA® vs placebo
CS29 studied both women and men

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 757 patients with nocturia and a high prevalence of nocturnal polyuria.

Two confirmatory phase III trials have been conducted: CS40[3] assessed 25 µg° in women, and CS41[4] assessed 50 µg° in men



25 µg°
Women once daily

50 µg°
Men once daily

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

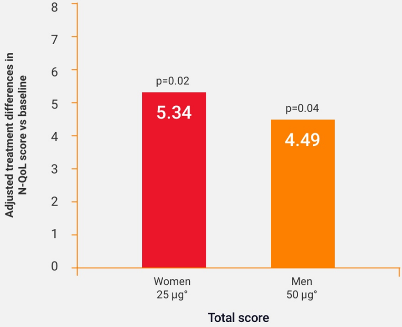
NOCDURNA® 25 µg° and 50 µg° is effective in women and men, respectively[3,4]

- **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 QOL

Significant improvement of nocturia-related QoL at month 3[3,4]



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 261 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 one of two doses of desmopressin vs placebo in 385 men in the United States and Canada with nocturia.

p-values are vs placebo. Quality of life was assessed using the nocturia quality of life and work productivity activity impairment questionnaire (a survey assessing 1 global and 12 disease-specific quality of life measures).
°50 µg is the approved dose in men and 25 µg is the approved dose in women

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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 Melt) 25 µg and tolterodine 4 mg:[2]

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

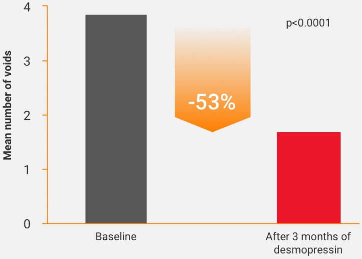
In a study of 137 men with LUTS/BPH of whom 62% were on concomittent BPH medication (α1 blockers and 5α reductase inhibitors):[8]

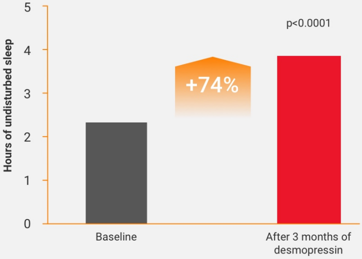
Desmopressin significantly reduced mean number of nocturnal voids **by 53%** at month 3 (p<0.0001)

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

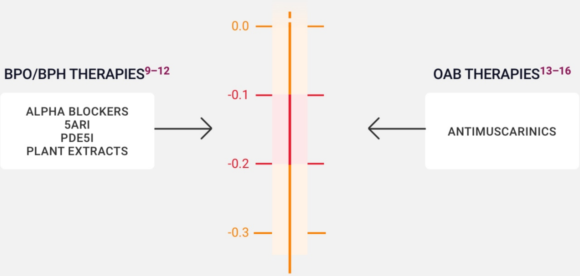
IMPACT OF DESMOPRESSIN ON NOCTURIA DUE TO NOCTURNAL POLYURIA IN MEN WITH LUTS/BPH[8]





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

CURRENT OAB/BPH THERAPIES DO NOT TARGET NOCTURNAL POLYURIA



BPO/BPH THERAPIES[9–12]

ALPHA BLOCKERS
5ARI
PDE5I
PLANT EXTRACTS

OAB THERAPIES[13–16]

ANTIMUSCARINICS

MODEST EFFICACY
on mid-void nocturia frequency vs placebo:

-0.1 and -0.2

BPH: benign prostate hyperplasia; OAB: overactive bladder; PDE5I: phosphodiesterase type 5 inhibitor; 5ARI: 5 alpha-reductase inhibitor

NOCDURNA® ADVERSE EVENTS SUMMARY

	Women[3]		**Men[4]**	
Summary of ALL treatment-emergent AEs	**Placebo** (n=126)	**25 µg°** (n=135)	**Placebo** (n=143)	**50 µg°** (n=119)
Total AEs, n (%)	57 (45%)	60 (44%)	58 (41%)	46 (39%)
Serious AEs, n (%)	2 (2%)[*]	0 (0)	1 (<1%)[†]	4 (3%)[‡]
AEs leading to SP: discontinuation, n (%)	1 (<1%)	4 (3%)	7 (5%)	4 (3%)
Severe AEs, n (%)	3 (2%)	1 (<1%)	2 (1%)	2 (2%)
Adverse drug reactions[+], n (%)	15 (12%)	26 (19%)	22 (15%)	23 (19%)

[+] Defined as an AE assessed by the Investigator as possibly/probably related to study drug

*Cellulitis and pulmonary embolism; [†] Pyrexia; [‡] Two patients with hyponatremia, one patient with acute myocardial infarction and one patient with osteoarthritis

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

● ○ ○

WHAT DO THE EXPERTS SAY?

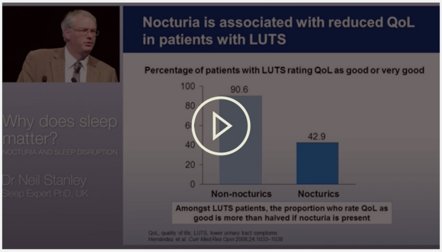
LEARN MORE

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



Nocturia is associated with reduced QoL in patients with LUTS

Percentage of patients with LUTS rating QoL as good or very good

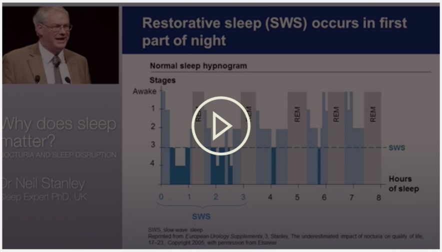
Amongst LUTS patients, the proportion who rate QoL as good is more than halved if nocturia is present

QoL, quality of life; LUTS, lower urinary tract symptoms
Hernández et al. *Curr Med Res Opin* 2008;24:1033–1038

How poor sleep has an effect on your patients

05:12

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



Restorative sleep (SWS) occurs in first part of night

Normal sleep hypnogram

SWS, slow-wave sleep
Reprinted from *European Urology Supplements*, 3, Stanley, The underestimated impact of nocturia on quality of life, 17–23., Copyright 2005, with permission from Elsevier

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

CONTACT US

SIGN UP FOR MORE INFORMATION ABOUT NOCDURNA®

Name Todd Cole Email todd_cole@gmail.com **SUBMIT**

DOWNLOAD THE SUMMARY OF PRODUCT CHARACTERISTICS

DOWNLOAD SMPC

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PHARMACEUTICALS

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