



SEIPELGROUP

FORMULATING INNOVATION

The Gender Gap in Lower
Urinary Tract Symptoms
and Bladder Control
Supplementation



Urox®: Clinically effective herbal for Men and Women

Seipel Group Pty Ltd is an Australian company committed to the research and development of specialized formulations to improve bladder control. Based in Brisbane, Australia, Seipel Group is led by the head formulator, Dr. Tracey Seipel, a naturopathic clinician, medical herbalist, clinical nutritionist with 30 years of formulation experience. Products include Urox®, Bedtime Buddy® (Urox® for children) and Prorox®, (Urox® plus other prostate support). For more information please visit: www.seipelgroup.com

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Executive Summary

Lower Urinary Tract Symptoms (LUTS) affect up to 50 million Americans and have emerged as a leading issue for healthy aging. According to the American Society of Consultant Pharmacists, kidney and bladder problems are the third most common chronic diseases in the aged after diabetes and arthritis. Poor bladder control tops the list of adverse conditions for senior quality of life. Loss of freedom, confidence and resultant early admittance to nursing care due to bladder control issues, which accelerate the aging experience, face many Baby Boomers now.

Phytomedicine therapies have been traditionally used in the treatment of symptoms of overactive bladder and urinary incontinence. Emerging clinical research into the use of phytomedicines demonstrates an increasing benefit from these approaches, without the side effects that are associated with prescription medications. However, few have been subjected to controlled clinical trials to evaluate their safety and efficacy with both men and women.

Contrary to popular perception, men and women have a similar prevalence of overactive bladder and symptoms such as occasional urgency, frequency and nocturia. And, although genito-urinary systems in men and women are very different, targeted bladder control supplementation is not necessarily gender specific.

However, symptoms of occasional incontinence or leaks and accidents, are unique in their causes and how they are experienced by gender with 'gender-specific' LUTS.

A 2002 EPIC study of 5 European countries showed a similar prevalence of the bladder storage problem, OAB (increased urinary urgency, frequency and

nocturia) in men and women. However, women have a higher likelihood of experiencing any form of urinary incontinence, and especially stress UI (up to 40% of women experience this after childbirth), that is often a result of pressure being placed on the pelvic floor during pregnancy and childbirth or with obesity or constipation.

Men, on the other hand, have a much higher rate of bladder voiding problems such as hesitancy, poor stream, straining, intermittency and dribbling, that is typically attributed to benign prostatic hypertrophy (BPH). The problem with male LUTS is that men may often assume the prostate is the only culprit, whereas half the time the primary



issue is OAB due to overactivity of the detrusor muscle resulting in excessive bladder contraction and the increased sensation of having to empty the bladder. Nocturia is a key symptom of OAB. Simply taking prostate support is only half the story. A paradigm shift in addressing male LUTS has occurred and a comprehensive prostate and bladder approach for men is now recommended.

Chronic bladder weakness is not an inevitable part of aging and effective dietary supplementation has been shown to improve control and quality of life. A thorough understanding of gender specific symptoms is essential when evaluating a comprehensive formula to address the ever increasing consumer demand for natural bladder control remedies.

The patented Urox® formulation is clinically proven to improve bladder control symptoms in both men and women. Urox® is the only natural formula to have shown statistically significant improvement in urinary incontinence in clinical research.

Combined with clinically researched condition directed ingredients Urox® can further enhance effectiveness for gender-specific LUTS issues.



Dr. Tracey Seipel
CEO

Dr. Tracey Seipel is a naturopathic clinician, medical herbalist, clinical nutritionist and diabetes educator with 30 years of experience in clinical practice settings.

During the 1990's, Dr. Seipel was a leader in establishing standards of education for Australian naturopathic colleges as an advisor to government boards with her involvement in the Queensland Naturopathic Association and Federation of Natural and Traditional Therapists.

During her research as product formulator for nutraceutical companies, she uncovered the significant prevalence and underreporting of urinary incontinence in women, and, then overactive bladder and incontinence in both men and women, which led to her pioneering this natural health category. Dr. Seipel is currently CEO of Seipel Group.

A recently published (January 2018) randomized, double-blind, placebo-controlled trial¹ conducted on 150 adults at three of Australia's leading universities showed the patented Urox® formula to be remarkably effective for both male and female symptoms of overactive bladder, stress and urgency urinary incontinence, with statistically significant results including:

- ✓ 23% of participants fully continent by 2 months
- ✓ Total average day frequency returned to normal
- ✓ 60% reduction in urinary urgency
- ✓ Halving of nocturia
- ✓ 60% average reduction in urinary incontinence (both stress and urge)
- ✓ 75% of Urox® users reduced their pad usage to one or less per day
- ✓ 84% Urox® users felt the treatment had benefitted them
- ✓ Improvement quality of life
- ✓ Results seen in as little as 2 weeks.



The study considered the benefit of halving nocturia (getting up to go at night) in reducing the additional debility of interrupted sleep in these patients highly clinically relevant. Also, reduction of adult diaper or pad usage to “precautionary” which is considered a significant quality of life improvement.

The study concluded that Urox® has the potential to deliver a natural, life-changing solution for widespread bladder control issues. No other clinically studied herbal formula has shown a statistically significant reduction of incontinence in clinical study.

Male And Female Bladder Control

The European EPIC study showed a prevalence of overactive bladder (OAB) of 11.8% with a 9.4% prevalence of urgency urinary incontinence (UI).² OAB prevalence was similar in men and women, affecting 11% men and 13% women.

The USA National Health and Nutrition Examination Survey (2001 to 2008) analysed data of 17,580 adults and found UI prevalence was 51.1% in women and 13.9% in men, with prevalence increasing over time.³ Research in Australia and China shows a similar trend. Women have a higher prevalence of total UI, stress UI, urgency UI and mixed UI (the combination of stress UI and urgency UI).



Country	Urinary Incontinence Prevalence
USA Women ³	51%
USA Men ³	14%
Australia ⁴	19%
China ⁵	22%
China ⁶	31%
China ⁷	19%

- Stress UI occurs without warning when stress is placed on the pelvic floor such as with coughing, laughing, jumping, sneezing or heavy lifting.
- Urgency UI occurs with warning when the individual has an urgency sensation and can't reach the restroom in time.
- Mixed urinary incontinence is a combination of stress and urge incontinence.

Women

Many women (40%) experience stress urinary incontinence (UI) for up to one year post-partum. UI affects approximately 25% at reproductive age, 50% post-menopause, and 50%-75% of women in nursing homes.^{4,8}

UI is so common in women that women often view UI as a 'normal' part of being female.⁹ Many with LUTS symptoms do not tell their doctor or even their partner about their condition.⁸ Many doctors do not question their patients about their bladder control; 50%-75% of incontinent community-dwelling patients never describe their symptoms to physician.^{3,10}

In a 2017 review paper on medical/surgical options and complications for women affected by UI, although 10-20% of women and up to 77% residing in nursing homes have UI, only 25% were found to seek or receive treatment for the condition.⁴

Anatomical differences

For many women, poor bladder control in the form stress UI is the result of stretching and weakening of the pelvic floor muscles during pregnancy and childbirth, although obesity and constipation and other factors can be involved. The pelvic floor muscles are then unable to support the internal and external

urethral sphincters that control urine release. The shorter urethra (urine outflow tube from bladder to outside of the body) in women mean women are more prone to urinary tract infections (UTIs) due to bacteria having a shorter distance to move from the outside of the body, along the urethra and into the bladder.

Women also experience overactive bladder (OAB) and urgency UI due to the excessive nervous stimulation of the bladder detrusor muscle.

In cases of UTI, the integrity of the bladder needs to be supported in conjunction with an antimicrobial approach with natural supplementation.



Adults Pads / Diapers

Adult diapers are reportedly the fastest growing household products business at \$8.9 billion globally with 48% growth projected 2015 – 2020. By 2020, the US diaper market is expected to reach US \$2.7 billion.^{11, 12} An increasing number of form-fitting female diapers, or absorbent underwear, options are entering the marketplace but dependence on diapers comes at a financial and environmental cost. Consumers can spend an average of US \$75 per month on these short-term, wasteful items that regardless of improvements still may become uncomfortable or embarrassing and require non-recyclable disposal.

Unfortunately, infant and adult diapers along with padded underwear are the third largest landfill waste product that take centuries to breakdown.¹³

The best solution is to reduce dependency on pads or diapers.

Treatment options

Pharmaceutical options for bladder control are often poorly tolerated due to the side effects of dry mouth, constipation, blurry vision, drowsiness and cognitive issues such as confusion and permanent memory loss/ dementia.

Research also supports the effectiveness of home-based Kegel, or pelvic floor, exercises, electrical and magnetic stimulation, and bladder retraining.



Recently published research assessed the effectiveness of Urox®, a proprietary herbal blend of *Crateva nurvala*, *Lindera aggregata* and *Equisetum arvense*, in reducing the symptoms of overactive bladder and urinary incontinence.¹ Urox was effective in reducing symptoms of stress, urgency and mixed urinary incontinence in women. It also improved OAB symptoms of urinary urgency, day frequency and nocturia with significantly improved quality of life.

Results

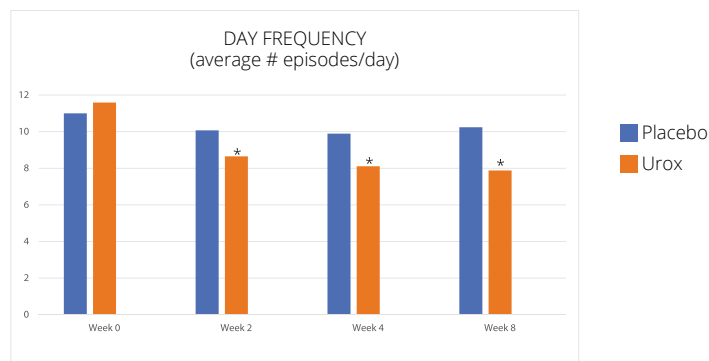
Table 1. Female demographic and symptom characteristics of study population at the start of the trial

Variable	Placebo	UROX
Participants	48	40
Age (years; mean ± SD)	61.52 ± 15.16	62.73 ± 14.69
Weight (kg; mean ± SD)	76.10 ± 20.63	73.83 ± 19.12
Day frequency ≥10	34	25
Nocturia ≥2	36	36
Urgency ≥2	43	34
Urgency incontinence ≥1	23	18
Stress incontinence ≥1	8	9
Any incontinence ≥1	32	25
Only two symptoms	15	15
Only three symptoms	18	14
All four symptoms	15	11

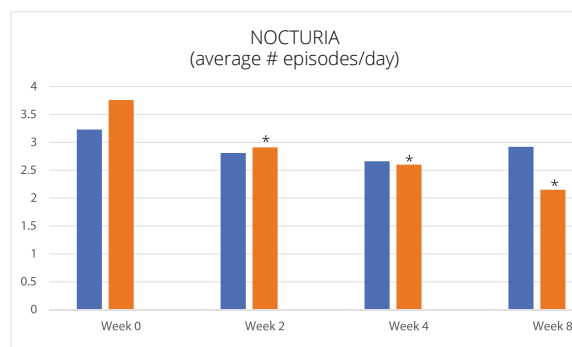


Table 2. Female OAB and Stress and Urgency UI symptom frequency as recorded from micturition diaries**Day frequency (n/day)**

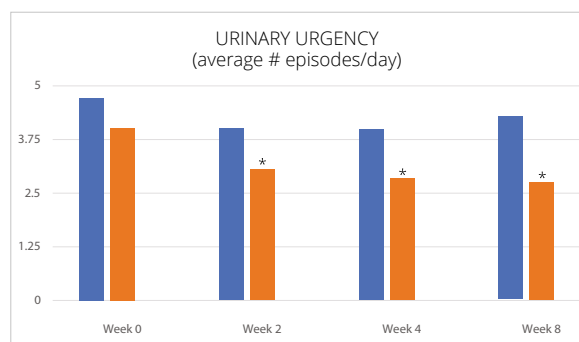
Variable	Placebo (mean ± SD)	UROX (mean ± SD)
week 0	11.00 ± 1.21	11.59 ± 1.80
week 2	10.07 ± 1.83	8.65 ± 2.37*
week 4	9.89 ± 1.97	8.11 ± 2.19*
week 8	10.24 ± 2.08	7.88 ± 2.28*

**Nocturia (n/day)**

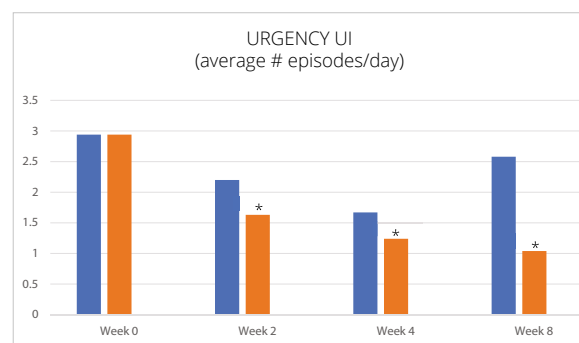
Variable	Placebo (mean ± SD)	UROX (mean ± SD)
week 0	3.23 ± 1.67	3.76 ± 1.55
week 2	2.81 ± 1.45	2.91 ± 1.92*
week 4	2.66 ± 1.20	2.60 ± 1.78*
week 8	2.92 ± 1.43	2.15 ± 1.70*

**Urgency (n/day)**

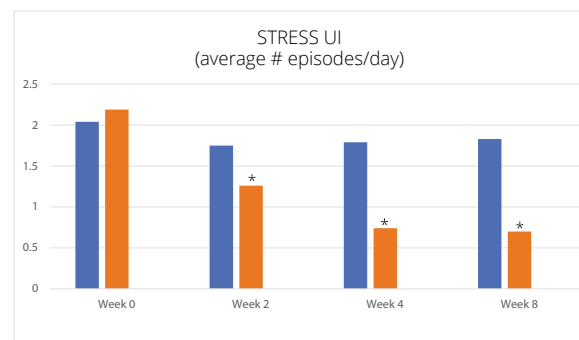
Variable	Placebo (mean ± SD)	UROX (mean ± SD)
week 0	4.64 ± 3.03	3.77 ± 1.65
week 2	3.75 ± 2.61	2.23 ± 1.76*
week 4	3.55 ± 2.65	1.74 ± 1.73*
week 8	4.08 ± 2.96	1.61 ± 1.85*

**Urgency Incontinence (n/day)**

Variable	Placebo (mean ± SD)	UROX (mean ± SD)
week 0	2.94 ± 3.10	2.94 ± 1.49
week 2	2.20 ± 1.51	1.63 ± 1.31*
week 4	1.67 ± 1.33	1.24 ± 1.23*
week 8	2.58 ± 2.70	1.04 ± 1.30*

**Stress Incontinence (n/day)**

Variable	Placebo (mean ± SD)	UROX (mean ± SD)
week 0	2.04 ± 1.40	2.19 ± 1.18
week 2	1.75 ± 1.57	1.26 ± 1.29*
week 4	1.79 ± 1.35	0.74 ± 0.98*
week 8	1.83 ± 1.47	0.70 ± 0.91*



* Significantly different between the two treatments at the specific time as analysed by mixed effects ordinal logistic regression.

Men

Historically, bladder control issues have been considered female-only problems but this is simply not the case. Although men experience significantly less UI, poor bladder control can have a dramatic negative impact. As with women, for men, the occurrence of LUTS, OAB and UI increases with age. Research shows 11% of men over the age of 40 have experienced an UI episode in the past year. For men over the age of 60 years, daily UI may be as high as 11% and in men over the age of 80 years daily UI reaches 32%.¹³

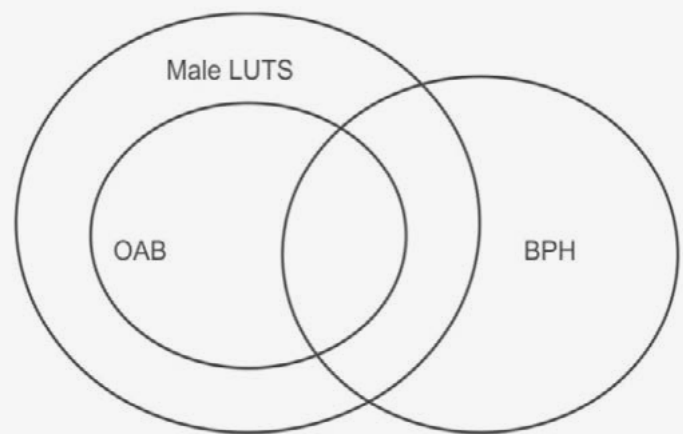
At 11%, almost as many men as women experience OAB. OAB is a bladder storage problem, where there is excessive neural stimulation of the bladder detrusor muscle resulting in urinary urgency or the need to rush for the restroom. This leads to increased urinary frequency (greater than 8 times in 24 hours), nocturia (getting up at night for the toilet) and if the toilet isn't reached in time, urgency UI.



Anatomical differences

Men also have a prostate gland sitting underneath and behind the urinary bladder. With age and increased androgen production, the prostate can enlarge and restrict the urethra, thereby restricting urine outflow. This causes voiding problems of weak urinary stream, increased straining, stop-start urination and dribbling post-voiding.

Although most men attribute their lower urinary tract symptoms (LUTS) to the prostate, 50% of the time their LUTS are due to OAB and storage problems as these men do not have urodynamically proven bladder outlet obstruction that may be attributed to BPH or other obstructive causes. Even in cases of benign prostatic hypertrophy (BPH), the enlarged prostate puts stress on the bladder, which then needs support. It is important the bladder receives the full attention it deserves with male LUTS.



Pads/Diapers

Male absorbent underwear and specially designed incontinence guards, which can be awkward to wear, are available. However, men have more difficulty accepting the wearing of adult diapers than women. Men tend to be less comfortable with loss of urinary control and do not generally consider it 'normal'. Men often say they feel plagued by urinary frequency at night and embarrassed by wearing of protective garments.

Treatment options

Men may be prescribed similar pharmaceutical as women (above) or male-specific treatments, which unfortunately are known to affect blood pressure and are associated with erectile dysfunction.

Urox® / Prorox®

Urox is effective in reducing symptoms of overactive bladder (OAB), urgency urinary incontinence (UI), nocturia and day frequency in men.

Table 3. Male demographic and symptom characteristics of study population at the start of the trial

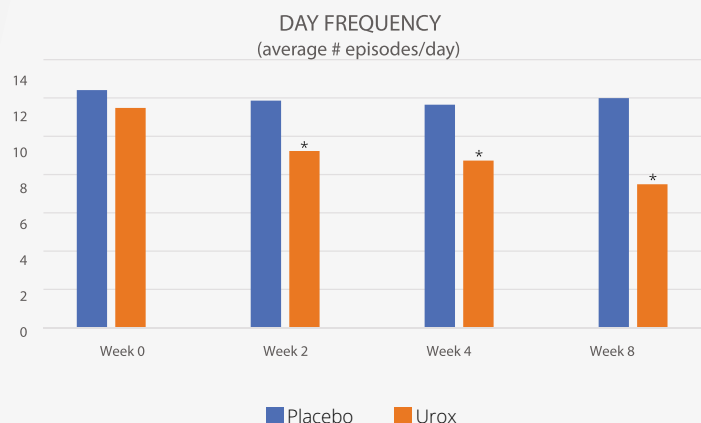
Variable	Placebo	UROX
Participants	27	35
Age (years; mean ± SD)	64.19 ± 10.68	66.63 ± 8.92
Weight (kg; mean ± SD)	84.78 ± 24.87	83.91 ± 17.46
Day frequency ≥10	23	25
Nocturia ≥2	24	34
Urgency ≥2	19	29
Urgency incontinence ≥1	10	14
Stress incontinence ≥1	1	1
Any incontinence ≥1	12	15
Only two symptoms	10	11
Only three symptoms	11	16
All four symptoms	6	8

Table 4. Male OAB and Urgency UI symptom frequency as recorded from micturition diaries

Male

Day frequency (n/day)

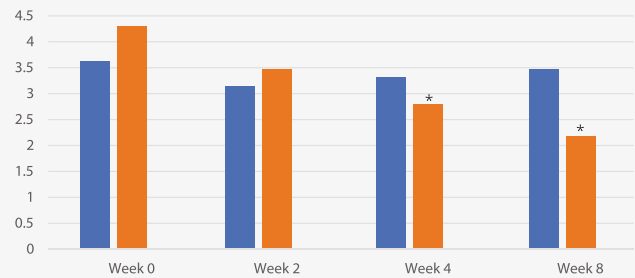
Variable	Placebo (mean ± SD)	UROX (mean ± SD)
week 0	12.41 ± 2.23	11.48 ± 1.25
week 2	11.86 ± 2.83	9.23 ± 2.67*
week 4	11.65 ± 2.65	8.73 ± 2.67*
week 8	11.99 ± 2.65	7.49 ± 2.02*



Nocturia (n/day)

Variable	Placebo (mean ± SD)	UROX (mean ± SD)
week 0	3.63 ± 1.24	4.29 ± 1.66
week 2	3.14 ± 1.23	3.47 ± 1.43
week 4	3.32 ± 1.34	2.80 ± 1.17*
week 8	3.47 ± 1.18	2.17 ± 1.25*

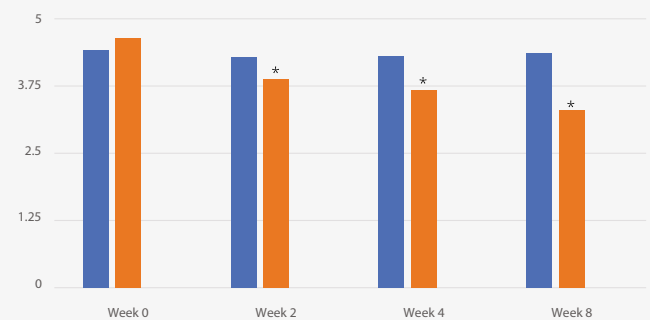
NOCTURIA
(average # episodes/day)



Urgency (n/day)

Variable	Placebo (mean ± SD)	UROX (mean ± SD)
week 0	3.68 ± 2.41	3.84 ± 2.02
week 2	3.42 ± 2.65	2.44 ± 2.42*
week 4	3.46 ± 2.77	2.05 ± 2.74*
week 8	3.56 ± 2.63	1.36 ± 2.75*

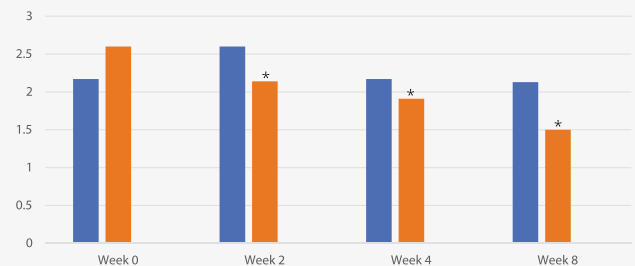
URINARY URGENCY
(average # episodes/day)



Urgency Incontinence (n/day)

Variable	Placebo (mean ± SD)	UROX (mean ± SD)
week 0	2.17 ± 1.12	2.60 ± 1.52
week 2	2.60 ± 1.61	2.14 ± 2.23*
week 4	2.17 ± 1.29	1.91 ± 3.35*
week 8	2.13 ± 1.38	1.50 ± 3.47*

URGENCY UI
(average # episodes/day)



* Significantly different between the two treatments at the specific time as analysed by mixed effects ordinal logistic regression.

■ Placebo ■ Urox

The Prorox formula combines Urox with clinically researched herbs and nutrients to support prostate health and relieve symptoms of BPH. Prorox contains Urox with CO₂-extracted Saw palmetto, Lycopene, Vitamin D3 Selenium and Zinc, to target the prostate AND bladder.

Patented Prorox expands on the proprietary Urox formula to improve bladder tone and

has an effect on the urinary tract resulting in reduction of frequency, urgency, nocturia and provides nutrients effective for prostate support.

Clinical research shows Prorox effective in reducing symptoms associated with BPH, urinary frequency, urgency and nocturia, as well as, improving IPSS (International Prostate Symptom Score) levels.

Urox® – Results/Research

Benefit and Willingness to Continue

Similarly, a significantly higher proportion of participants in the Urox® group (84%) reported they had benefited from the treatment compared to 18% of the placebo group, and 77% of participants in the Urox® group indicated their willingness to continue with Urox® compared to 29% in the placebo group

Frequency - Day and Night (nocturia)

Results show that 60% of participants in the Urox® group reported normalization (i.e., 8 or less micturitions/day) of their excessive day frequency after week-8 of the trial, compared with 11% of the placebo group. Similarly, for nocturia, 24% of the Urox® group became symptom free at the end of the trial (with improvements observed as early as 2 weeks), compared to less than 2% of the placebo group.

Urinary Urgency

For urinary urgency, 21% of Urox® participants reported no urgency at the end of the trial period, compared to only 5% in the placebo group.

Urinary Incontinence

23% percent of participants in the Urox® group reported they were incontinence free at the end of 8 weeks compared to 7% in the placebo group.

Sleep

Halving nocturia within two months of treatment reduces the additional debility of interrupted sleep in these patients, and is considered highly clinically relevant.

Convenience

Reductions in day urinary frequency, urgency and incontinence are also very clinically relevant particularly to patients whose lives can be continuously interrupted on a daily basis by needing to use toilet facilities within a close proximity of their whereabouts.

- Effectiveness on symptoms (clinical research)
- Reduction of diaper use
- Combines well with other ingredients (Prorox)
- No side effects / good compliance

- Responsibility of our industry to present consumers with natural solutions that have the ability impact distressing or debilitating conditions
- Huge market segment, pent-up demand and lack of understanding of the prevalence of conditions or potential opportunity?

Quality Of Life

Those affected by poor bladder control tend to modify their lifestyle to cope. They wear dark clothing on the lower half to cover in case of accidents and wear adult pads/diapers/absorbant underwear. Sleep is disrupted and maintaining an exercise routine often proves difficult due to the necessity of having ready access to a restroom, resulting in lower daytime energy and cardiovascular health.

Poor bladder control usually means travelling no more than one hour at a time in case of the need to change their pad/diaper or find a restroom. Socialising is impacted which negatively affects mental health and overall quality of life. Issues with sexuality are also associated

with urinary incontinence and eventually, sufferers become reclusive, isolated and have a significant reduction in quality of life. Urinary incontinence is a leading cause for elderly admittance to nursing care.

Urox is shown to improve quality of life across all parameters tested with participants experiencing:

- Less bother
- Better coping
- Less concern/worry
- Better sleep
- Improved socialising
- Less urinary distress
- Reduced incontinence

Quality of Life

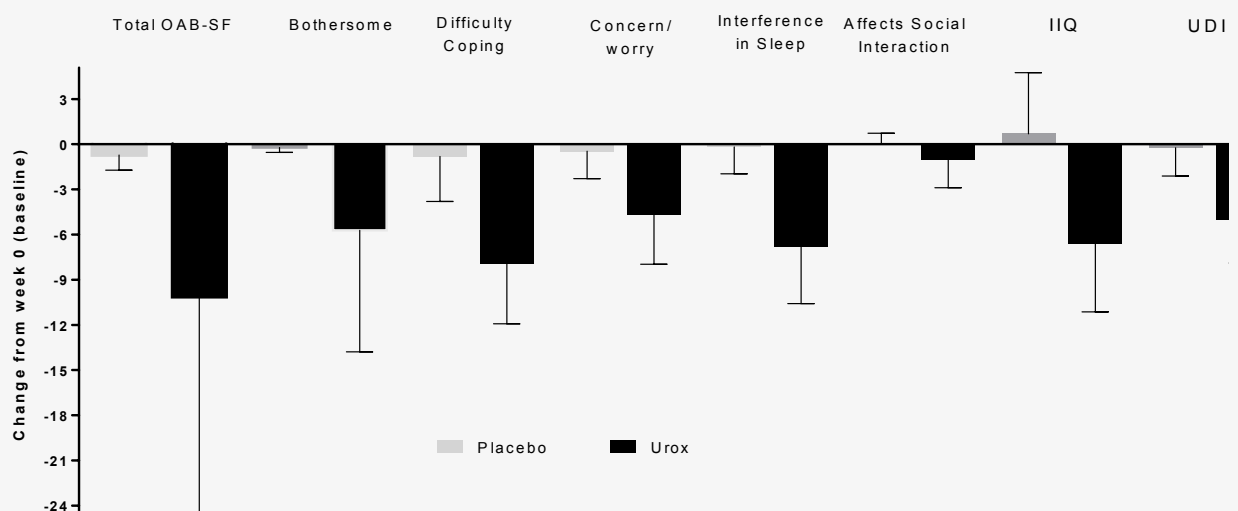


Figure 5. HR-QOL scores at week-8: Placebo vs Urox® (p<0.01)

The Solution

Urox®

- 8+ years of safe usage
- Successful clinical trials
- More effective than alternatives
- Very well tolerated
- No side effects like anticholinergics/antimuscarinics
- Cost effective when compared to pads or other medications

User Benefits

The remarkable results Urox® has shown for reducing incontinence, including the use of pads or diapers, in just eight weeks has significant clinical and practical value. Considering the demonstrated benefits, lack of serious adverse events or side-effects of drugs along with a high rate of patient compliance and participant satisfaction, the utility of Urox® by clinicians, supplement retailers and manufacturers is worthy of consideration.

Urox



Pad / Diaper Reduction

Approximately 40% of the participants in both groups reported using diapers at the start of the study. At this time (i.e., week-0) 28% of placebo and 23% of Urox® participants reported using diapers for more than just precautionary measures (i.e., more than 1 diaper per day).

At the end of the study, 26% participants in the placebo group continued to use more than one pad/diaper a day compared to only 6% in the Urox® group. In addition, the number of individuals using moderate/heavy pads throughout the study reduced in the placebo group from 20 at baseline to 19 at the end of the study period, whereas for the Urox® group, this number reduced from 18 at baseline to 6 participants at week-8.

Urox® has demonstrated significant efficacy and tolerability in the treatment of UI and symptoms of OAB for men and women, without side effects

typically associated with anticholinergic/antimuscarinic medications.

When considering ingredients for a bladder control formula prioritize those which have been clinically tested on both men and women, then evaluate your business to assess if additional ingredients targeting gender-specific symptoms are more compatible with your current line.

The expertise needed to determine if the stand-alone Urox® formula or Urox® in combination with other ingredients is available at Seipel Group.





Please contact us to learn about our private label partnership, bulk purchase and worldwide distribution opportunities or for further information regarding the development of our award-winning formulations and clinical research.

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***"Quality of life delivered by innovative,
natural, clinically proven products."***



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