

Femalgen™

Softgels

proprietary blend of pumpkin seed extract + soy germ isoflavones

*The clinically proven answer for
urinary incontinence, overactive bladder,
and frequent nighttime urination*



SOFT GEL
TECHNOLOGIES, INC.



THE SURPRISINGLY COMMON PROBLEM NO ONE'S TALKING ABOUT

Judging by how little urinary dysfunction gets talked about, you might assume it's not a particularly pressing health issue. The truth is that urinary incontinence, overactive bladder, and nocturia are much more common problems than most people realize. Unfortunately, the majority of people who experience urinary dysfunction don't mention it to their friends — let alone their physicians — because of its embarrassing nature.

COMMON URINARY PROBLEMS AND THEIR CAUSES

- Urinary incontinence** is the accidental leakage of urine. It can be triggered by many things, such as coughing, laughing, sneezing, or physical exercise. The problem can profoundly impact quality of life, as people who have "accidents" often feel shame and embarrassment and may avoid situations that involve social interaction.

Urinary incontinence usually develops when the muscles that control the bladder become weakened — whether from pregnancy, childbirth, chronic coughing, or age — allowing urine to leak out. In men, urinary incontinence may also be caused by an enlarged prostate.
- Overactive bladder** is characterized by the sudden urge to urinate, even when the bladder is only half-full. People who suffer from overactive bladder often need to rush to the bathroom.

In normal urination, the bladder muscles contract when the bladder is full, squeezing urine out. When the bladder is overactive, these contractions happen involuntarily, even if there is only a little bit of urine in the bladder. Sometimes overactive bladder leads to urinary incontinence. In this case, it is called "urge incontinence."
- Nocturia** is the technical term for excessive nighttime urination, defined as awakening from sleep to urinate twice or more during the night. Not only is nocturia inconvenient, it can trigger insomnia.

Nocturia can be caused by any number of things, such as an enlarged prostate, several medications, or a host of diseases. However in seniors, nocturia may have a more simple cause. As we get older, we produce less of a hormone that causes us to retain fluid, so we actually manufacture more urine. Additionally, our bladders lose their ability to store urine with age.

FACTS AND FIGURES

- 1 in 4 women between the ages of 30 and 59 has experienced some urinary incontinence. The problem gets worse with age; nearly 40% of women over age 50 struggle with incontinence.¹
- 1 in 6 adults over age 40 suffers from overactive bladder.²
- More than 80% of people in their 60s — and 90% of those 80 and older — experience nocturia.³

HOW FEMALGEN™ CAN HELP

Femalgen™ features Go-Less™ — a proprietary combination of EFLA® 940 water-soluble pumpkin seed extract with SoyLife® soy germ isoflavone extract — which has been clinically proven to:

- Slash the number of urinary incontinence episodes
- Improve the symptoms of overactive bladder
- Reduce the number of nighttime trips to the bathroom
- Improve sleep satisfaction

Soft Gel Technologies is pleased to offer Femalgen™ in an off-the-shelf softgel formulation.



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ABOUT THE INGREDIENTS

EFLA® 940 pumpkin seed extract

Pumpkin seeds have been used for hundreds of years to treat bladder and kidney problems. Modern double-blind studies have found that pumpkin seed extract causes improvements in urinary flow rate, voiding time, and residual urine volume in men suffering from benign prostatic hyperplasia (enlarged prostate).⁴ In 1985, the German Commission E approved pumpkin seed as a therapeutic agent for the treatment of irritable bladder and early-stage prostate hypertrophy.

EFLA® 940 is a proprietary pumpkin seed extract that contains the full spectrum of water-soluble compounds contained within the whole seed. The patented HyperPure® manufacturing process used to produce EFLA 940® ensures highly selective removal of the fat-soluble components, delivering a very stable finished ingredient.



SoyLife® soy germ isoflavones

Soybeans are a naturally concentrated source of isoflavones. These beneficial phyto-nutrients attach to estrogen receptors, allowing them to exert estrogenic or anti-estrogenic effects as needed. Numerous studies have demonstrated that soy isoflavones can reduce hot flashes,⁵ protect against bone loss,⁶ and support cardiovascular health⁷ in menopausal and post-menopausal women. Initial research indicates they may also help promote prostate health in men.^{8,9}

The subject of more than 30 clinical studies, SoyLife® is the only patent-protected soy germ isoflavone on the market for use in dietary supplements. Yet more than an isoflavone concentrate, SoyLife® offers the complete spectrum of beneficial compounds found in the germ of the soybean.



Femalgen™ contains the same dosage of EFLA® 940 pumpkin seed extract and soy germ isoflavones proven to improve urinary incontinence, overactive bladder, and frequent nighttime urination in three human clinical trials.



CLINICAL RESEARCH ON FEMALGEN™

Clinical Study #1: Nighttime Urination and Incontinence in Women

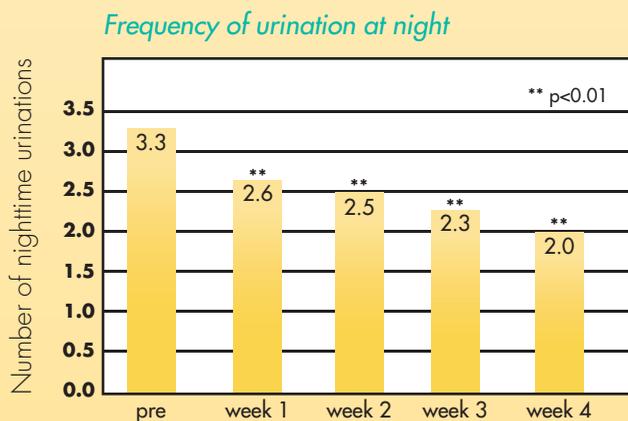
An open clinical study evaluated the effects of the active ingredients in Femalgen™ in 39 post-menopausal women.¹⁰ The trial lasted seven weeks: one week of observation, and six weeks of treatment. Four different outcome measures were studied:

1. Frequency of urinary incontinence
2. Frequency of urination during the day
3. Frequency of urination at night
4. Sleep satisfaction

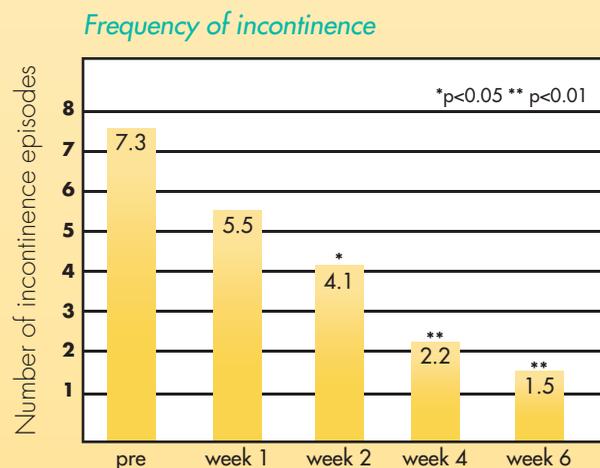
Results

- When it came to reducing episodes of urinary incontinence, the combination of pumpkin seed extract and soy germ isoflavones knocked the ball out of the park. During the initial one-week observation period, subjects experienced an average of 7.3 urinary incontinence episodes per day. By the end of week six, that number had plummeted to just 1.5 episodes — a 79% drop!
- Frequency of daytime and nighttime urination also decreased significantly over the course of six weeks — 16% and 39% respectively.
- With fewer nighttime trips to the bathroom came improved sleep satisfaction. Whereas only 16% of subjects reported feeling satisfied with the quality of their sleep during the observation period, 60% felt satisfied at the end of the six-week trial.
- At the study's completion, three-quarters of the participants were rated as either "improved" or "markedly improved" on a scale of global improvement.

What was extraordinary was how quickly the formulation worked. Within one to two weeks, all four outcome measures were markedly reduced; the improvements only got better with time.



Sogabe H, et al. (2001) Jap. Med. Pharm. Sci. 46 (5) 727-37



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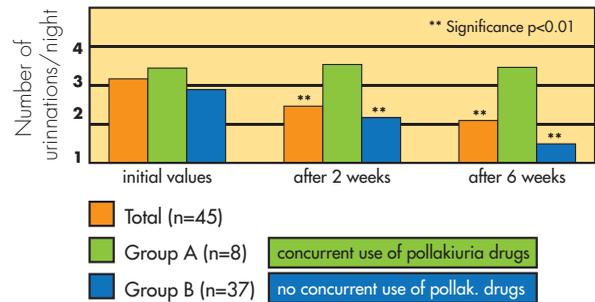
Clinical Study #2: Nighttime Urination in Men

Another clinical study tested the efficacy of the active ingredients in Femalgen™ on nocturia (frequent nighttime urination) in 45 senior men, either with or without concurrent use of drugs for nocturia.¹¹ The seven-week trial included one week of observation and six weeks of treatment.

Results

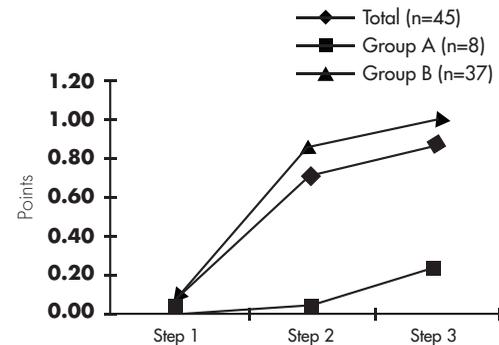
- Men taking pumpkin seed extract plus soy germ isoflavones in combination with drugs for nocturia did not experience much change in their condition after six weeks. However, those taking the supplements alone experienced a dramatic 40% improvement in nocturia.
- Sleep satisfaction among the supplements-only group also received a boost. On a scale of -2 ("unsatisfied") to 2 ("satisfied"), the average sleep satisfaction at the beginning of the study was 0.1. After six weeks, it rose to 1.04 — a significant increase.
- Excellent efficacy was demonstrated by the improvement level in subjective symptoms. By the end of the trial, a full 86.7% of subjects were evaluated as "improved" or "significantly improved."

Decrease in nighttime urination frequency

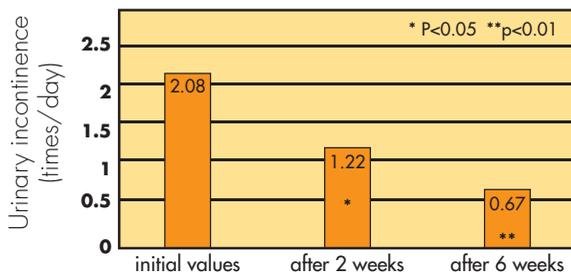


Terado T. et al. (2004) Jap. Med. Pharm. Sci. 46 (5) 727-737

Change in sleep satisfaction Level

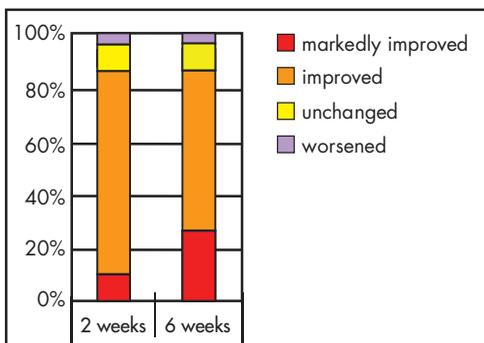


Decrease in stress incontinence episodes



Yanagisawa E, et al. (2003) Jap. J. Med. Pharm. Sci. 14;(3):313-322

Improvement level in subjective symptoms



Clinical Study #3: Overactive Bladder in Women

A final open clinical trial was undertaken to see if the active ingredients in Femalgen™ could improve symptoms of overactive bladder in women.¹² Forty-eight patients between the ages of 35 and 84 were studied for seven weeks: one week of observation and six weeks of treatment.

- The combination of pumpkin seed extract plus soy germ isoflavones produced a remarkable reduction in daily episodes of stress incontinence due to overactive bladder. During the observation period, subjects averaged 2.08 incidents per day. At the end of the six-week trial, that number plummeted to 0.67 — a 68% decrease.
- Patients with the largest number of stress incontinence episodes showed the greatest improvement.
- Overall improvement was high, with 87.5% of subjects rated either "improved" or "remarkably improved" by the study's end.

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MECHANISM OF ACTION

In vitro and *in vivo* studies indicate that the ingredients in Femalgen™ support normal urinary function in two ways:

1. Conserving testosterone in men and women

Testosterone is an anabolic hormone, meaning it helps build muscle — including the pelvic muscles that support bladder control.¹³ The enzyme aromatase is responsible for converting testosterone into estradiol. *In vitro* studies have demonstrated that isoflavones and EFLA® 940 pumpkin seed extract inhibit aromatase, helping maintain testosterone levels.

Dihydrotestosterone (DHT) is a potent androgen that plays a role in the development of enlarged prostate in men. The enzyme 5-alpha reductase is involved in the conversion of testosterone into DHT. *In vitro* experiments have shown that EFLA® 940 pumpkin seed extract inhibits 5-alpha reductase, aiding in the preservation of testosterone levels.

2. Relaxing the bladder muscles

Nitric oxide is a gas that plays a role in smooth muscle relaxation. When the bladder is relaxed, its capacity to hold urine increases. An *in vivo* study found that EFLA® 940 pumpkin seed extract decreases in-bladder pressure.¹⁴ The researchers theorized that the arginine contained in the extract increased the production of nitric oxide, contributing to bladder relaxation.

SAFETY

The safety of Femalgen™ has been confirmed in three human clinical trials. The comparison of pre- and post-supplementation blood work, as well as adverse side effect monitoring, showed that Femalgen™ was well-tolerated and highly safe.

PATENTS

The pumpkin seed extract used in Femalgen™ — EFLA® 940 — is produced through a patented manufacturing process that ensures highly selective removal of the fat-soluble components, so it is very stable.

The soy germ isoflavone extract in Femalgen™ — SoyLife® — is the only patent-protected soy germ isoflavone on the market for use in dietary supplements.

DELIVERY SYSTEM

Soft Gel Technologies is pleased to offer Femalgen™ as an off-the-shelf formulation in a soft gelatin capsule.





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<http://www.webmd.com/urinary-incontinence-oab/oab-8/oab-causes>
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- ¹³ Ho MH, et al. Anabolic effects of androgens on muscles of female pelvic floor and lower urinary tract. *Curr Opin Obstet Gynecol*. 2004 Oct;16(5):405-9.
- ¹⁴ Hata K, et al. Effects of pumpkin seed extract on urinary bladder function in anesthetized rats. *Jpn J Med Pharm Sci*. 2005;54(3):339-345.

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FEMALGEN™ HIGHLIGHTS

Available exclusively from Soft Gel Technologies, Femalgen™ softgels contain a proprietary combination of EFLA® 940 water-soluble pumpkin seed extract with SoyLife® soy germ isoflavone extract.

Femalgen™ has been clinically proven to:

- Slash the number of urinary incontinence episodes
- Improve the symptoms of overactive bladder
- Reduce the number of nighttime trips to the bathroom
- Improve sleep satisfaction

INDICATIONS

- Urinary incontinence (stress incontinence)
- Overactive bladder (urge incontinence)
- Nocturia (frequent nighttime urination)

WHY CHOOSE FEMALGEN™?

- **Clinically proven.** Femalgen™ is backed by three published human clinical trials, all of which found the product effective for its studied use. In fact, in all three studies, at least 75% of patients showed significant improvements in their condition.
- **Fast-acting.** In all three human studies, Femalgen™ delivered results quickly. Some outcome measures, such as frequency of nighttime urination and sleep satisfaction, improved within just one week of taking the product. Others, such as number of urinary incontinence episodes, showed significant improvement within two weeks.
- **Dose-matching.** Femalgen™ soft gels contain the same dosage of EFLA® 940 pumpkin seed extract and SoyLife® soy germ isoflavones proven to improve urinary incontinence, overactive bladder, and frequent nighttime urination in three human clinical trials.
- **High-quality.** Femalgen™ contains the highest quality ingredients. EFLA® 940 is a proprietary pumpkin seed extract that contains the full spectrum of water-soluble compounds contained within the whole seed. SoyLife® is the only patent-protected soy germ isoflavone on the market for use in dietary supplements, offering the complete spectrum of beneficial compounds found in the germ of the soybean.
- **Safe.** The comparison of pre- and post-supplementation blood work in human clinical trials, as well as adverse side effect monitoring, showed that Femalgen™ was well-tolerated and highly safe.

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