

Confidence.

Control.

FemalgenTM

for mature women

SOFT GEL
TECHNOLOGIES, INC.[®]

Urinary Incontinence

The Center for Bladder Control defines urinary incontinence (UI) as a demonstration of involuntary urine loss that is sufficient to be a social or hygienic problem. UI is not a topic of conversation in most homes. In fact, many women will not even discuss the problem with their physicians. It is believed to be a vastly underdiagnosed and underreported condition, according to the Agency for Healthcare Research and Quality. It is estimated that over 12 million Americans suffer from urinary incontinence. Women are affected by the disorder more frequently than men; one in 10 women under age 65 suffers from UI. Older women are more prone to UI; approximately twenty percent of women over age 65 are incontinent. In the US, the direct and indirect costs associated with UI are estimated to be 16 billion dollars annually.

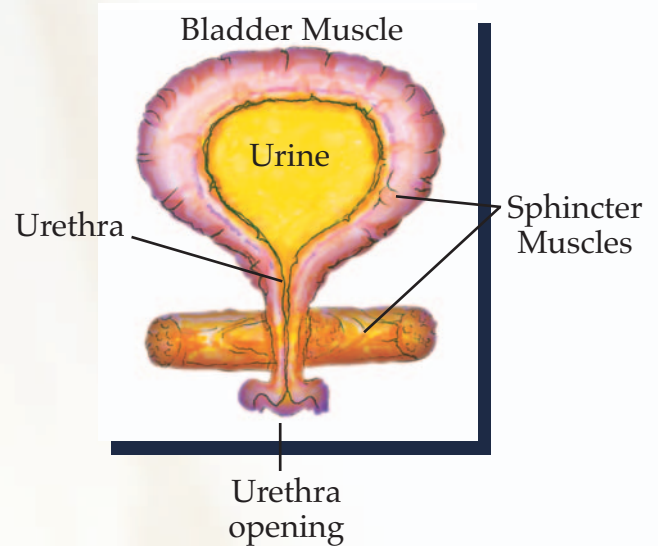
For many people, UI affects their emotional, psychological, and social well-being. Many people are afraid to participate in normal daily activities that might take them too far from a toilet. The majority of UI can be treated successfully. Soft Gel Technologies, Inc.[®] is proud to announce **Femalgen™**, a clinically tested nutraceutical that helps combat the debilitating symptoms of UI.

Urinary Bladder

The urinary bladder is a triangle-shaped, hollow, and muscular organ that acts as a reservoir for urine. Urine is waste removed from the blood by the kidneys. Urine flows from the kidneys through the ureters (pair of tubes) to the bladder, which is located in the lower abdomen. A normal human bladder has a capacity of 400 to 500 ml. Urine leaves the body through another

tube (the urethra) at the bottom of the bladder.

Urination is controlled by sphincters, ring-like bands of muscles, located at the base of the bladder and in the walls of the urethra. The sphincters close off the neck



of the bladder and the urethra—like a tie around the neck of a balloon—so that the bladder will not leak urine. During urination, the sphincters relax and open the passage for urine. At the same time, the muscle of the bladder wall contracts and forces the urine out of the bladder. When urination is finished, the sphincters contract and the bladder stops contracting.

Emptying of the bladder is controlled by parasympathetic and sympathetic nerve fibers. The brain signals the bladder muscles to tighten, which squeeze urine out of the bladder. At that time, the brain signals the sphincter muscles to relax to let urine exit the bladder through the urethra. The bladder's walls relax and expand to store urine, and contract and flatten to empty urine through the urethra.

Classification of UI

Incontinence is classified by the symptoms or circumstances occurring at the time of the urine leakage. Urinary incontinence may occur for only a short time (acute), or it may be chronic. Acute UI may be caused by a urinary tract infection, a drug side effect, or bladder stones. This condition is typically easily resolved once the cause is determined and addressed. Chronic UI may be caused by muscle weakness in the urinary tract or by damage or a malfunction in the urinary tract (structural problems with the urinary tract that affect the flow of urine or the nerves that control urination).

Chronic UI can be classified into:

- **Stress incontinence** caused by exerting pressure on the abdomen during exercise, sneezing, coughing, or laughing. Physical changes resulting from pregnancy, childbirth, and menopause often cause stress incontinence. It is the most common type of urinary incontinence in women. Stress UI usually occurs when the pelvic muscles are weakened, for example, by childbirth or surgery.
- **Overflow incontinence** caused by obstruction of the bladder or urethra, or a bladder that doesn't contract properly. As a result, the bladder does not empty completely, leading to frequent urine leakage. This often occurs in men and can be caused by an obstruction of urinary flow, such as an enlarged prostate gland or tumor.
- **Urge incontinence** occurs when an individual feels a sudden need to urinate and cannot control the urge to do so. As a consequence, urine is involuntarily lost before the individual can get to the toilet. It is most common in the elderly, and may be a sign of an infection in the kidneys or bladder.

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- **Functional incontinence** caused by physical or cognitive disability, such as Alzheimer's disease, Parkinson's disease, arthritis, or multiple sclerosis. Individuals have control over their own urination but cannot make it to the bathroom in time, because their health condition stifles their mobility.
- **Reflex incontinence** caused by neurological impairment. Individuals with reflex incontinence lose control of their bladder without warning. The nervous system sends signals to the bladder telling it when to start and stop emptying. When the nervous system is impaired, the bladder may contract involuntarily, expelling urine without warning, or may cease contractions completely, causing urinary retention.

Depending on the cause, chronic UI may be treated with targeted exercises, absorbent pads, medications, or surgery. Medications include estrogen hormone replacement therapy, which can help improve pelvic muscle tone in post-menopausal women. Other medications are sometimes prescribed to relax the bladder muscles or to tighten the urethral sphincter.

Femalgen™

Femalgen™ is a cutting-edge nutraceutical from Soft Gel Technologies, Inc.® It is a combination of soybean germ and pumpkin seed extracts.

Soybean Germ Extract

It is commonly known that soy is a plant (phyto) estrogen. Considered to be a weak estrogen, phytoestrogen differs from the stronger estrogen normally produced endogenously (within the body). Estrogen replacement therapies mimic naturally-synthesized estrogen. There are many perimenopausal and postmenopausal women who, due to health considerations, are unable to take pharmaceutical estrogen replacement therapy. This leaves them with very few options on how to control the symptoms that are associated with this period of their lives. Femalgen™ is an excellent alternative. For many women, this plant-derived supplement helps to relieve them of hot flashes, as well as a host of other symptoms.

Pumpkin Seed Extract

The use of pumpkin seed dates back to the 16th century, where it was used to treat diseases of the urinary tract. In the 1980s, studies were conducted on pumpkin seed for the treatment of bladder problems.

Pumpkin seed can be broken down into its starting components of linoleic acid, oleic acid, palmitic acid, stearic acid, carotenoids, tocopherols, and phytos-

terols. Lignans and phenols have also been found in pumpkin seeds.

Femalgen™ contains lipid-free pumpkin extract, which is characterized by a lignanic and phenolic glycosides content. They, like soy, belong to the family of phytoestrogens. The importance of lignans is that they can be identified in a woman's urine, proving that they can reach the estrogen receptors of the urethral mucosa.

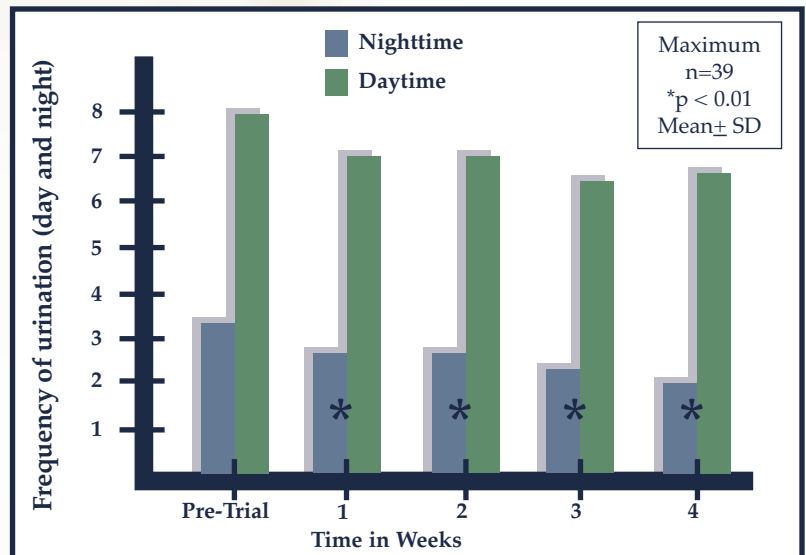


Chart 1

Clinical Study

The safety and efficacy of Femalgen™ were assessed in an open clinical trial on 39 postmenopausal women, aged 52 to 86 years, who reported two or more micturition episodes (the passage of urine) during the night, excluding an episode at leaving bed in the morning.

The study lasted for a total of seven weeks. The first week was for observational

Table 1

| | before dosing | week - 1 | week - 2 | week - 4 | week - 6 |
|---|----------------|------------------|------------------|------------------|------------------|
| Frequency of urination during the night (n) | 3.3 ± 1.6 (39) | 2.8 ± 1.5** (39) | 2.5 ± 2.2** (31) | 2.3 ± 1.9** (39) | 2.0 ± 2.3** (28) |
| Frequency of urination during the daytime (n) | 8.0 ± 2.6 (39) | 7.0 ± 2.5** (39) | 6.8 ± 2.9** (31) | 6.5 ± 2.0** (39) | 6.7 ± 2.3** (36) |

Mean ± SD
 **p < 0.01
 *p < 0.05
 n = number of subjects

Table 2

| | before dosing | week - 1 | week - 2 | week - 4 | week - 6 |
|--|---------------|-----------|------------|-------------|-------------|
| Frequency of urinary incontinence (n=16) | 7.3 ± 8.3 | 5.5 ± 3.4 | 4.1 ± 3.5* | 2.2 ± 2.2** | 1.5 ± 2.7** |

Mean ± SD
**p < 0.01
*p < 0.05
n = number of subjects

purposes only. The dietary supplement used was a processed food tablet that contained a combination of pumpkin seed extract and soybean germ extract. During weeks 1 and 2, the subjects received a total of 10 tablets daily, which provided 875 mg pumpkin seed extract and 167 mg soybean germ extract. By the third week of the study, the dosage was decreased to 6 tablets per day with a corresponding decrease in the active ingredients to 525 mg and 100 mg, respectively. The daily tablets were divided into two doses, in the morning and evening.

Several subjective measurements were evaluated. They included:

- Frequency of urination during the night
- Frequency of urination during the day
- Frequency of urinary incontinence during the daytime – number of episodes of involuntary leakage of urine during the period from getting up in the morning to bedtime
- Degree of satisfaction rated as fulfilled, somewhat fulfilled, not fulfilled
- Other measurements included vital signs (body weight, blood pressure, pulse rate), hormone determinations, hematologic tests, blood chemistry, and urinalysis.

Results

Chart 1 and Table 1 show that Femalgen™ markedly improved (p<0.01) the frequency of urination during the night and daytime after the first week, followed by continuing improvement at the second week, and no further improvement after the fourth week.

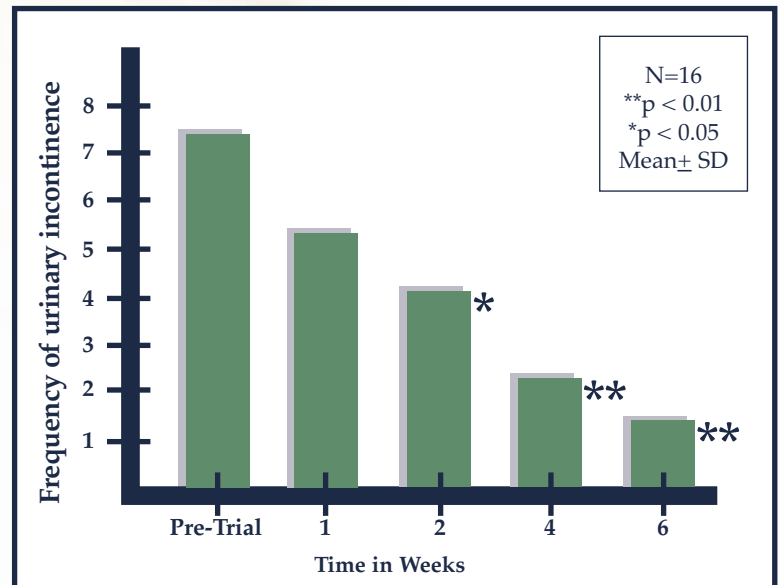


Chart 2

Chart 2 and Table 2 show that the frequency of urinary incontinence was improved (p<0.05) at week 2, and markedly improved (p<0.01) at week 4.

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The global improvement rates of study participants based on subjective symptoms and objective findings were evaluated in a subgroup of 33 subjects who had 2 to 4 episodes at night per day during the observation period. Twenty seven subjects (81.8%) were rated as "improved" or better at week 6.



Summary

SGTI® **Femalgen**™ has been clinically tested for safety and efficacy, and is clearly a breakthrough in the symptomatic improvement of urinary incontinence for post-menopausal women. A natural combination of pumpkin seed and soybean germ extracts, **Femalgen**™ is the only product available that has demonstrated such dramatic results. Your customers deserve the opportunity to have an active, fulfilling life. For further inquiries, please call our toll free number.

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