Product Description

Libifem™

APPLICATIONS

Libifem™ is a product containing a fenugreek extract recommended to:

- Promotes healthy female sexual vitality.
- Support sexual cognition and arousal in women.
- Reduces menopausal symptoms (hot flushes and night sweats).

COMPOSITION

Libifem™ is obtained from the seeds of fenugreek (*Trigonella foenum-graecum*) through a special extractive process which allows extracting fenugreek active principles in a specific proportion. **Libifem™** is standardized with more than 50% Fenuside™.

DESCRIPTION

Fenugreek seeds are well known for their traditional use to treat asthenia, hyperlipidemia and hyperglycemia. Several studies have demonstrated the effectiveness and safety of their consumption.

Libifem™ is a special extract that contains saponins that support female sexual health. This extract has been clinically proven to promote woman healthy libido, sexual vitality and desire. According to the results, **Libifem™** has a positive effect on sexual behaviour that can be attributed to its content in Fenuside™.

CLINICAL TRIAL

In 2011 the University of Queensland (Australia) carried out an 8-week randomized, placebo-controlled, double-blind study on 80 healthy females in stable relationships. The study covered metabolism, hormone levels and sexual functioning.

The trial was conducted on healthy menstruating women, with regular menstrual cycles, aged 21 to 49.

The participants were randomised to an oral dose of 300 mg **Libifem™**, as active treatment, or placebo twice at day over 2 menstrual cycles, starting in follicular phase of the menstrual cycle.

Sexual function was measured using approved standard questionnaires at baseline prior to treatment, month 1 (mid-point) and at month 2, which tests five domains of sexual function: *sexual cognition, sexual arousal, sexual experience, orgasm* and *sexual relationship*.

The study also measured perceived stress levels and fatigue (with separate scores for general fatigue, emotional fatigue, physical fatigue, mental health and overall vigour).

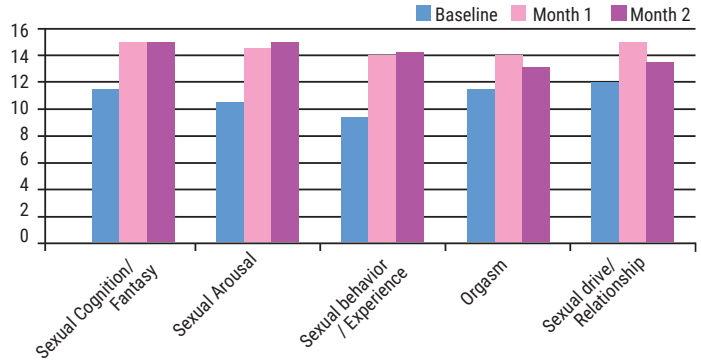

Fig. 1 Domain scores for **Libifem™** group at baseline, month 1 and month 2.

The results showed that the active group of **Libifem™** showed significant increases in all tested domains, while the placebo group did not show significant changes at the end of the second month of stud, but steady state for the majority of sexual domains. (Fig. 1)

In addition **Libifem™** group increased intercourses frequency from 1-2 times per month to average of once per week, meanwhile the frequency of sexual activity in the placebo group remained the same at month 2, at 1-2 times per month. When compared the results obtained by the use of **Libifem™** respect to the placebo group, it can be appreciated a positive effect in all the tested domains, which demonstrated the efficacy of **Libifem™** treatment on sexual function in this group of healthy menstrual women.

There was no significant intergroup difference between active treatment group and placebo groups at month 2 on the hormone levels forming the chain of steroid synthesis. However, oestradiol showed an increase from 202.9 – 327.2 pmol/L in **Libifem™** group that was significant respect placebo group at month 2. (Fig. 2)

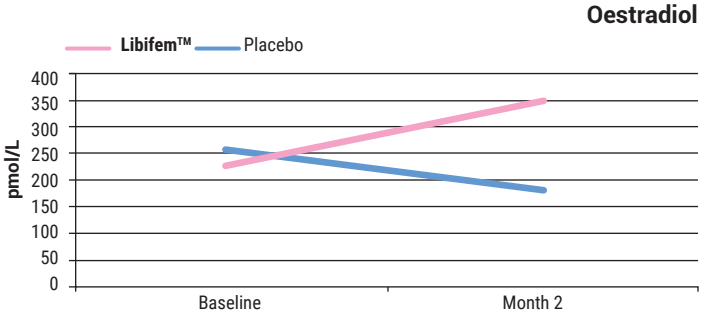

Fig. 2 Oestradiol results at baseline and month 2 in **Libifem™** and placebo groups (p<0.5).

In 2015 was carried out a double-blind, randomised, placebo-controlled trial involving 104 healthy women experiencing menopausal symptoms aged between 40 and 65 years of age conducted in Brisbane (Australia) to assess the effectiveness **Libifem™**, a specialized *Trigonella foenum-graecum* seed extract on reducing menopausal symptoms in otherwise healthy women and any associated effect on serum sex hormones. The active treatment was **Libifem™** at a dose of 600mg/day for 12 weeks.

Participants were included in the study if they were aged between 40 and 65 years old and were experiencing menopausal symptoms. The symptom profile included the presence of hot flushes or night sweats and scoring greater than mild on the MENQOL and able to adhere to protocol requirements and provide informed consent. The clinical trial did not include any women that were currently using other investigational product(s).

The primary outcome measure was reduction in menopausal symptoms, assessed by the validated questionnaire MENQOL and a patient reported diary of hot flushes and night sweats.

The secondary outcomes included assessment of sex hormones (LH, FSH, progesterone, oestradiol, prolactin, DHEA, and testosterone) as well as SHBG and lipid profile.

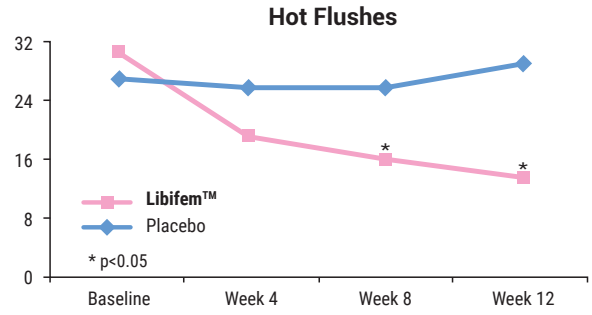

Fig. 3 a

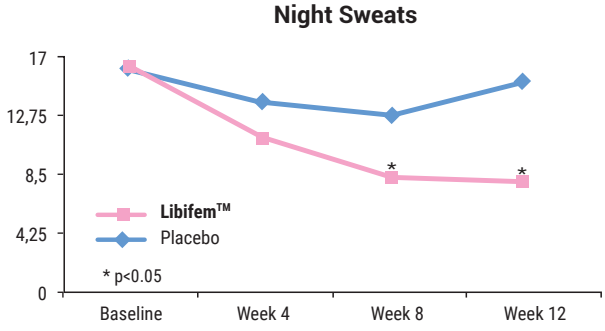

Fig. 3 b

Libifem™ was assessed for safety by liver / electrolyte function and full blood count (FBC).

The results showed a significant reduction in menopausal symptoms in the active treatment group compared to placebo as assessed by the total MENQOL score. This was reflected in significant improvements in all the MENQOL domains: vasomotor, psychosocial, physical and sexual domain. The vasomotor domain data correlated with the results of the patient reported diary of hot flushes, with the active treatment group having significantly less day time hot flushes and less night sweats compared to placebo at 12 weeks. (Fig. 3 a & b)

Libifem™ was well tolerated with all the safety parameters, full blood count and liver function as well as lipid metabolism, remaining in healthy reference range.

Researchers concluded that **Libifem™** is a safe and effective treatment for reducing menopausal symptoms over 12 weeks in otherwise healthy women. The product was well tolerated and there were no adverse effects reported by participants during the study.

Participants also assessed the effect of treatments answering 3 questions related to the sexual domain: vaginal dryness, sexual desire and avoiding intimacy. The results showed an improvement in the group treated with **Libifem™** but did not reach statistical significance. There was very little change reported by participants in the placebo group for these questions (Fig. 4). Nevertheless, when the 3 questions were grouped together, the sexual domain showed significant improvement in active treatment group compared to placebo group at 12 weeks.

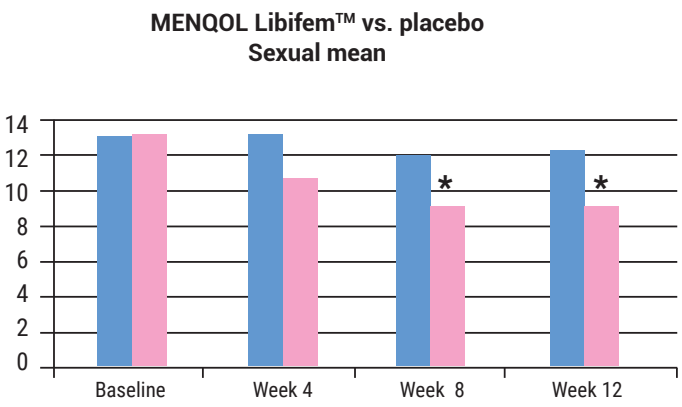

Fig. 4 Placebo Libifem™ * Significant

SAFETY

Libifem™ is safe and effective treatment for supporting sexual functioning in healthy menstruating women, including those using *oral contraceptive pill*, without altering the duration of the menstrual cycle.

RECOMMENDED DOSES

We recommend 600 mg of **Libifem™** per day taken in two times (2 x 300 mg) before or during the main meals.

BIBLIOGRAPHY

Rao A., Steels E. *et al*. Influence of a Specialized *Trigonella foenumgraecum* Seed Extract (Libifem), on Testosterone, Estradiol and Sexual Function in Healthy Menstruating Women, a Randomised Placebo Controlled Study. *Phytother. Res.* (2015). (wileyonlinelibrary.com) DOI: 10.1002/ptr.5355

Steels E., Steele M.L. *et al.* Efficacy of a Proprietary *Trigonella foenumgraecum* L. De-Husked Seed Extract in Reducing Menopausal Symptoms in Otherwise Healthy Women: A Double-Blind, Randomized, Placebo-Controlled Study. *Phytother. Res.* (2017). (wileyonlinelibrary.com) DOI: 10.1002/ptr.5856