FemCOOL™

WHITE PAPER

FemCool™ is a proprietary, patent-pending formulation that cools hot flashes and promotes perimenopausal and menopausal health.

Clinically proven to promote hormone balance.

valensa
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Menopause is defined as the period of time occurring 12 months after a woman's last menstrual cycle and generally happens between the ages of 40 – 60, with the average age of menopause occurring at 51[1]. The process of menopause starts several years before, in a transition period called perimenopause and is the period where the ovaries gradually begin to make less estrogen. The symptoms of perimenopause can range from minor to extreme and can be very problematic to premenopausal women. Symptoms include: hot flashes, breast tenderness, lower sex drive, fatigue, irregular periods, vaginal dryness, urine leakage and urgency, mood swings and trouble sleeping. An estimated 6,000 women reach menopause every day (over 2 million per year) in the United States alone and 75 – 85% of these women experience hot flashes and night sweats. Traditionally, women have been prescribed Hormone Replacement Therapy (HRT) to help with these symptoms. In recent years, several studies have shown that women taking HRT drugs have a higher risk of breast cancer, heart disease, stroke and blot clots. The largest study was the Women's Health Initiative (WHI), a 15-year study tracking over 161,800 healthy, postmenopausal women. The study found that women who took the HRT therapy had an increased risk of heart disease[2].

FemCool™ provides perimenopausal and menopausal women relief from hot flashes and other menopause-related discomforts. This proprietary, patent-pending synergistic formulation contains HMRlignan™which has been shown to substantially reduce the frequency of hot flashes by up to 55% and the severity by up to 79%.* HMRlignan™ is a highly bioavailable natural plant-based estrogen that assists the female body in balancing estrogen levels; which is associated with reduction of hot flashes and improved bone mineral density. This proprietary blend also contains DIM, which supports estrogen metabolism. The Tomato Lycopene & Cranberry Extract also provide cellular protection in the breast & cervical tissue.

Key Features

- Derived from Norwegian spruce, HMRlignan™ is shown to be 1000 times more bioavailable than lignans found in Flaxseed and other sources.
- Our unique formulation contains DIM, which provides an estrogen balancing effect for women's bodies.
- We include Cranberry Extract and Tomato Lycopene.
- FemCool™ also contains important B Vitamins to support energy and cellular metabolism.

HMRLignan™

HMRLignan™ is derived from the Norway spruce and contains 7-Hydroxymatairesinol (7-HMR), a natural plant lignan, and the direct metabolic precursor of the mammalian lignan enterolactone. Enterolactone exhibits weak estrogen activity. So what does HMRLignan™ have to do with enterolactone? Essentially, human intestinal flora converts 7-HMRLignan™ into mammalian enterolactone, thus HMRLignan™ is an enterolactone precursor that delivers estrogen-like activity to humans. Since this conversion takes place in the intestines, it is readily absorbed into blood plasma.

Enterolactone then mimics the effects of estrogen without the common side effects found in traditional hormone replacement therapy. In a 2002 Canadian study which compared flaxseed dietary supplement (a weaker 7-hydroxy-matairesinol enterolactone precursor) versus hormone replacement therapy in hypercholesterolemic menopausal women, the study showed that flaxseed improved mild menopausal symptoms[3].

The three major naturally occurring estrogens in women are estrone (E1), estradiol (E2), and estriol (E3). Estradiol is the strongest estrogen and potentially poses the highest peri- and post-menopausal risk. Enterolactone has also been shown to down-regulate estradiol bio-availability and potential reduction of estradiol-dependent breast cancer cell proliferation. In fact, a recent study has shown that postmenopausal women with breast cancer have a significantly lower amount of the weaker 2-OH estrogen versus the 16a-OH estrogen, compared to postmenopausal women without breast cancer. Therefore it is postulated that postmenopausal women with higher levels of the 16a-OH estrogen in their bodies are at higher risk for developing breast cancer. This study indicated that HMRLignan™ works to modulate estrogen levels, while also working to modulate estradiol levels which may reduce the chance of developing breast cancer. Thus plant based 7-HMRLignan™ and its resulting conversion to enterolactone in the human gut provides a safer alternative to standard HRT therapy while reducing hot flashes.

HMRLignan™ is standardized to deliver 800mg/gram of lignans which compares very favorably to unrefined flax seed which contain less than 50% of the lignan precursors available in HMRLignan™, in fact you would have to take 20 – 30 grams of unrefined flaxseed each day to obtain the same benefit derived from 10 – 30 mg of HMRLignan! A single-blind parallel pharmacokinetic and dose-comparison study was conducted on 22 post-menopausal females who were not receiving HRT. Consumption of a 36mg/d dose of HMRLignan resulted in a 50% reduction in hot flashes through 8 weeks. At doses as low as 10 mg/day, HMRLignan produced a marked elevation in enterolactone concentration in plasma while well-designed clinical studies highlight the safety of this product, and unlike flax seed, it contains no secoisolariciresinol, the precursor of enterodiol.

DIM

DIM (Diindolylmethane) is derived from the digestion of indole-3-carbinol found in cruciferous vegetables such as broccoli, brussel sprouts, cabbage and kale and can increase adaptive responses by regulating hormone metabolism (particularly estrogen). In addition, DIM can also convert the stronger estradiol into a weaker form of estrogen and increase the metabolism of 2-hydroxy estrogens.

DIM has been shown to exert anti-carcinogenic effects in many experimental animal models as well as in human breast cancer cell lines with no tumor induction at high doses in any cell line. Therefore a great deal of research is underway to determine the exact mechanism associated with the unusual activity of DIM. The National Cancer Institute is also supporting clinical trials on DIM to determine if the product can be used as an adjunct therapy to prevent the further spread of the disease in breast cancer patients. This makes it an ideal ingredient in a women's health product.

Lycopene

Cancer, by definition, is the manifestation to aberrant cells in which DNA has undergone unfavorable and permanent mutations; therefore one strategy to avoid carcinogenesis is to prevent DNA damage from occurring, particularly in those people who have a compromised P53 DNA repair gene.

In a randomized double-blind placebo controlled intervention study, 37 healthy non-smoking post-menopausal women aged 50 – 70 were randomly assigned to 1 of 5 groups and were instructed to consume a daily dose of mixed carotenoids (4 mg each of beta-carotene, lutein and lycopene) or a 12 mg dose of either beta-carotene, lutein or lycopene or placebo for 56 days. Lymphocyte DNA damage was measured by using single cell gel electrophoresis (COMET ASSAY). At day 57, all carotenoid-supplement groups showed significantly lower endogenous DNA damage than at baseline ($p<0.01$), whereas the placebo group did not show any significant change in DNA damage profiling. These results indicate that a combination of carotenoids significantly decreases DNA damage by dietary intervention and that a larger dose of a single carotenoid also exerts protection against DNA damage[4].
In Sridevi et al. they were also able to show that 8 weeks of lycopene supplementation in health adults significantly decreased DNA damage as evidence by decreased urinary excretion of 8-hydroxydioxoguanosine (8-OHdG)3. Furthermore, an in vitro study by Levi et al. showed that lycopene was 4 – 10 fold more potent that alpha or beta-carotene respectively in inhibiting the proliferation of endometrial, breast and lung cancer cell lines. Further in vitro studies indicate that lycopene is able to prevent progression of tumorigenesis[5] in human prostate cancer cells lines and that lycopene was the only common carotenoid to exhibit such effects.
In Kotsopoulos et al., (2005) the authors explored the use of lycopene in order to modulate the deleterious mutations of hereditary BRCA1 or BRCA2 from conferring its normal high lifetime risk of developing breast cancer by decreasing DNA damage or by enhancing DNA repair, and concluded that the prevention of hereditary breast cancer through diet is an attractive complement to the current management strategies[7].

It is well known that 17-B-estradiol (E2) as well as the soy-based phytoestrogen genistein are both important risk factors for breast cancer. In Hirsch et al. (2007) they showed that lycopene inhibited breast and endometrial cancer cell proliferation induced by either E2 or genistein and suggested that dietary lycopene may attenuate the deleterious effect in hormone-dependent malignancies.

Although a great deal of mechanistic work is continuing to unravel the biological mechanisms by which lycopene exerts its clearly established down regulation of breast cancer cell proliferation, emerging science strongly suggests that dietary intake of lycopene is recommended for all women and in particular those with familial histories of breast cancer.

FemCool™

A proof of concept study was conducted to evaluate the effectiveness of a dietary supplement formulation on the reduction and severity of hot flashes in women.

Design:

Two female subjects experiencing symptoms of perimenopause, particularly hot flashes, were given a formula containing HMR Lignan, DIM (Diindolylmethane), Lycopene, and Cranberry juice powder.

- Female Subject A - 46 year old female who was experiencing 3-4 severe hot flashes per day. The most severe hot flashes were awakening her at night, accompanied by severe sweating.
- Female Subject B - 50 year old female who experienced 9-12 hot flashes throughout the day, ranging from mild to severe. The most severe hot flashes usually occurring in the afternoon and evening.
- Each woman was given a 30 day count bottle of the capsules to be taken once per day with water.

TRIAL A- *Proprietary blend of HMR Lignan, DIM, Lycopene, and cranberry powder given to subject A and B.*

Result: *By day 2, both female subjects were free of both hot flashes and night sweats*

TRIAL B- *Proprietary blend of HMR Lignan, DIM, and cranberry powder given to subject A.*

Result: After 3 days, Female Subject A started to get what she described a mini-hot flashes. The frequency was similar to what she was experiencing before treatment, but the severity was about 50% reduced. Therefore, lycopene, when combined with HMRLignan™ may have an important role in this formulation for hot flash control.

A series of additional trials are ongoing to further explore the effectiveness of the each ingredient either alone or in combination in the reduction of hot flashes.

It is a known fact that the symptoms of menopause can cause a tremendous amount of stress, both physically and emotionally for the women who are experiencing it. Unfortunately, until recently, there were no healthy alternatives to the harsh hormone replacement therapy drugs. We have discovered a unique formula that uses the synergistic effects of lycopene, DIM and HMRLignan™ to help alleviate these symptoms quickly and safely.

Not only does the FemCool™ formula deliver relief, but is beneficial for maintaining breast health in aging women.

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