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Warmi® and Its Effects on Symptoms of Menopause

Introduction:

Warmi® is a nutritional formulation of glucosinolates, beta-sitosterol and citrus flavonoids as active ingredients. The purpose of this study is to monitor menopausal symptoms and observe the earliest onset of symptom relief when using Warmi®. In addition, once discontinuing Warmi®, monitoring to see if or when menopausal symptoms return.

Methods:

The applicants were screened for menopausal symptoms using the Meridian Valley Laboratory questionnaire. The criteria included women with menopausal symptoms between the ages of 40 and 60 years old. They were excluded if they had chronic renal or hepatic disease, uncontrolled hypertension or uncontrolled diabetes, current or history of cancer, or any form of hormone therapy for a minimum of 30 days prior to starting the Warmi® study. There were a total of 30 participants with 24 completing the study, 2 dropping out due to adverse health (described below) and 4 that stopped filling out the questionnaire, never finishing the study. The participants filled out the Menopausal Symptom Questionnaire twice weekly for 4 weeks (2 weeks while on Warmi® and 2 weeks post-Warmi®) having 9 questionnaires total. The results were analyzed according to severity of menopausal symptoms, tallied for the groups and reported in the results section.

Results:
The results are broken into two groups depending on the color of the capsule and therefore represents where the product was manufactured. While taking Warmi®, each typical symptom of menopause was subjectively assessed and analyzed for improvement as well as if there were any changes or worsening and after discontinuing, how quickly the symptoms changed.

RED Capsules (Table 1 and 2): 10 Participants – During Warmi Intake and Two Weeks After Discontinuation

Hot flashes/night sweats – 7 reported improvements, while 3 reported no change. Of the 7 participants, the majority reported a two category improvement, for example from severe to mild hot flashes/night sweats, or from moderate to no hot flashes and night sweats. After discontinuation, 4 reported worsening of symptoms, while 1 reported improvement and 5 reported no change.

Vaginal dryness – 6 reported improvements, while 1 had a worsening symptom and 3 reported no change. After discontinuation, 4 reported worsening of symptoms, while 6 reported no change.

Heart palpitations – 5 reported improvements, while 2 had worsening symptoms and 3 reported no change. After discontinuation, 2 reported worsening of symptoms, while 4 reported improvement and 4 reported no change.

Sleep disturbance – 5 reported improvements, while 5 reported no change. The improvements were by one category, for example from moderate to mild sleep disturbance. After discontinuation, 4 reported worsening of symptoms, while 1 reported improvement and 5 reported no change.

Low libido – 4 reported improvements, while 6 reported no change. After discontinuation, 3 reported worsening of symptoms, while 7 reported no change.

Anxiety – 5 reported improvements, while 5 reported no change. After discontinuation, 6 reported worsening of symptoms, while 4 reported no change.

Depression – 5 reported improvements, while 1 reported worsening of symptoms and 4 reported no change. After discontinuation, 3 reported worsening of symptoms, while 1 reported improvement and 6 reported no change.

Irregular periods – 1 reported improvement, while 1 reported worsening of symptoms and 8 reported no change. After discontinuation, 2 reported improvement and 8 reported no change.

Bleeding changes – 3 reported improvements, while 7 reported no change. After discontinuation, 1 reported improvement and 9 reported no change.

Sore, painful breasts – 3 reported improvements, while 7 reported no change. After discontinuation, 2 reported worsening of symptoms, while 1 reported improvement and 7 reported no change.

Fibrocystic breasts – 1 reported improvement, while 9 reported no change. After discontinuation, 1 reported worsening of symptoms, while 9 reported no change.

Hair loss – 2 reported improvements, while 8 reported no change. After discontinuation, 2 reported worsening of symptoms, while 1 reported improvement and 7 reported no change.

Headaches – 6 reported improvements, while 1 reported worsening of symptoms and 3 reported no change. After discontinuation, 2 reported worsening of symptoms, while 8 reported no change.

Stress – 6 reported improvements, while 4 reported no change. After discontinuation, 5 reported worsening of symptoms, while 5 reported no change.

Mood swings – 7 reported improvements, while 3 reported no change. After discontinuation, 5 reported worsening of symptoms, while 1 reported improvement and 4 reported no change.

Facial hair – 2 reported improvements, while 8 reported no change. After discontinuation, 1 reported worsening of symptoms, while 1 reported improvement and 8 reported no change.

Acne – 2 reported improvements, while 1 reported worsening of symptoms and 7 reported no change. After discontinuation, 2 reported worsening of symptoms, while 1 reported improvement and 7 reported no change.

Sugar cravings – 7 reported improvements, while 3 reported worsening of symptoms and 4 reported no change. After discontinuation, 4 reported worsening of symptoms, while 3 reported improvement and 3 reported no change.

Fatigue – 9 reported improvements, while 1 reported worsening of symptoms and 4 reported no change. After discontinuation, 4 reported worsening of symptoms, while 1 reported improvement and 5 reported no change.

Poor memory – 5 reported improvements, while 1 reported worsening of symptoms and 8 reported no change. After discontinuation, 2 reported worsening of symptoms, while 1 reported improvement and 7 reported no change.

Difficulty concentrating – 9 reported improvements, while 5 reported no change. After discontinuation, 2 reported worsening of symptoms, while 1 reported improvement and 7 reported no change.

CLEAR Capsules (Table 1 and 2): 14 participants – During Warmi Intake and Two Weeks After Discontinuation

Hot flashes/night sweats – 9 reported improvements, while 5 reported no change. After discontinuation, 7 reported worsening of symptoms, while 4 reported improvement and 3 reported no change.

Vaginal dryness – 5 reported improvements, while 1 reported worsening of symptoms and 8 reported no change. After discontinuation, 3 reported worsening of symptoms, while 1 reported improvement and 10 reported no change.

Heart palpitations - 4 reported improvements, while 2 reported worsening of symptoms and 8 reported no change. After discontinuation, 3 reported worsening of symptoms, while 11 reported no change.

Sleep disturbance – 10 reported symptoms, while 4 reported no change. After discontinuation, 6 reported worsening of symptoms, while 2 reported improvement and 6 reported no change.

Low libido – 5 reported improvements, while 9 reported no change. After discontinuation, 6 reported worsening of symptoms, while 3 reported improvement and 5 reported no change.

Anxiety – 8 reported improvements, while 2 reported worsening of symptoms and 4 reported no change. After discontinuation, 3 reported worsening of symptoms, while 1 reported improvement and 10 reported no change.

Depression – 8 reported improvements, while 6 reported no change. After discontinuation, 2 reported worsening of symptoms, while 2 reported improvement and 10 reported no change.

Irregular periods – 2 reported improvements, while 1 reported worsening of symptoms and 11 reported no change. After discontinuation, 1 reported worsening of symptoms, while 2 reported improvement and 11 reported no change.

Bleeding changes – 1 reported improvement, while 1 reported worsening of symptoms and 12 reported no change. After discontinuation, 1 reported worsening of symptoms, while 1 reported improvement and 12 reported no change.

Sore, painful breasts – 4 reported improvements, while 1 reported worsening of symptoms and 9 reported no change. After discontinuation, 2 reported worsening of symptoms, while 2 reported improvement and 10 reported no change.

Fibrocystic breasts – 1 reported improvement, while 1 reported worsening of symptoms and 12 reported no change. After discontinuation, all 14 reported no change.

Hair loss – 2 reported improvements, while 12 reported no change. After discontinuation, 1 reported worsening of symptoms, while 13 reported no change.

Headaches – 7 reported improvements, while 2 reported worsening of symptoms and 5 reported no change. After discontinuation, 2 reported worsening of symptoms, while 1 reported improvement and 11 reported no change.

Stress - 9 reported improvements, while 1 reported worsening of symptoms and 4 reported no change. After discontinuation, 5 reported worsening of symptoms, while 3 reported improvement and 6 reported no change.

Mood swings – 10 reported improvements, while 4 reported no change. After discontinuation, 4 reported worsening of symptoms, while 1 reported improvement and 9 reported no change.

Facial hair – 3 reported improvements, while 1 reported worsening of symptoms and 10 reported no change. After discontinuation, 3 reported improvement and 11 reported no change.

Acne – 3 reported improvements, while 1 reported worsening of symptoms and 10 reported no change. After discontinuation, 2 reported worsening of symptoms, while 12 reported no change.

Sugar cravings – 7 reported improvements, while 3 reported worsening of symptoms and 4 reported no change. After discontinuation, 4 reported worsening of symptoms, while another 4 reported improvement and 6 reported no change.

Fatigue – 9 reported improvements, while 1 reported worsening of symptoms and 4 reported no change. After discontinuation, 2 reported worsening of symptoms, while 2 reported improvement and 10 reported no change.

Poor memory – 5 reported improvements, while 1 reported worsening of symptoms and 8 reported no change. After discontinuation, 1 reported worsening of symptoms, while 2 reported improvement and 11 reported no change.

Difficulty concentrating – 9 reported improvements, while 5 reported no change. After discontinuation, 1 reported worsening of symptoms, while 4 reported improvement and 9 reported no change.

As mentioned previously, there were two patients who discontinued the study after consulting with a physician:

> Patient 1: S.C. (7-1-11 Nurse note) = Pt d/c per cardiologist instruction due to onset of severe menopausal sx (chest palpitations, hot flashes increased). She was put on the vivelle dot.
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> Patient 2: C.D. (5-31-11 via email from patient): After 1 week of using the red capsules of Warmi®, she had spotting and cramps similar to having a period. Menopausal symptoms worsened. Warmi® made her bladder feel infected. Her ovaries hurt and throb. It mimicked the feeling of a fibromyalgia attack for her where her joints started to ache and burn. The total amount of capsules consumed were 21 and symptoms started after 15 capsules. The bladder infection sensation resolved after discontinuing Warmi®.

Knowing that one of Warmi®'s actions was to stimulate the FSH receptor, one question that was wondered during the course of the study was: could the Warmi® have added too much phytoestrogen to a patient who has too low progesterone, exacerbating a progesterone deficiency?

After the first two patients ended the study, they continued using Warmi®, the clear capsules bought from LaneLabs. Within 2 weeks, communication by the patients revealed a different effect while taking the clear capsules. Per Andrew Lane, one month supplies of the red capsules were given to both patients and results monitored. Below are the communication notes:

> PT A: Pt unhappy with the clear capsules: July 19, 2011 per telephone conversation: The clear capsules made her nauseous (even with food in her stomach). She felt nothing like she did while on the red capsules. The clear capsules tasted funny and did not relieve her hot flashes or her miserable mood.
> After giving her a month of the red capsules – she noted that within 3-4 days she felt back to her "normal" with very few hot flashes. The red capsule did not make her nauseous and they quickly relieved the hot flashes.
>
> Patient B: Patient really responded to the red capsules and did not to the clear capsules. She used a month supply of the clear capsules. I gave her another month of red capsules and within days she noticed the hot flashes, night sweats, and mood improve.

At the end of each questionnaire, a section encouraged written feedback while on Warmi®. Document 1 lists the participants A-X, the questionnaire day and any comments. There were some positive, but unexpected, acknowledgments such as softer skin while on Warmi®, more motivation, better creativity throughout the day, and weight loss, all which reversed upon discontinuing Warmi®.

A note needs to be made about bone loss as a symptom that was excluded from the report even though it is listed on the questionnaire. This symptom seemed to cause much confusion with participants because many have not had bone density checked yet and definitely not checked in the one month before and after this study.

In summary, the symptoms that showed improvement while on Warmi® *for the most number of women* include: hot flashes/night sweats, sleep disturbance, low libido, stress, mood swings,

and fatigue, with moods swings being the most (17 out of 24 showed improvement). The symptoms that were improved for the least number of women while on Warmi®, were symptoms that would take longer than 2 weeks to notice change, such as irregular periods, sore/painful breasts, fibrocystic breasts, facial hair, acne, hair loss, and poor memory. The symptoms that report worsening for a very small amount of participants while on Warmi® were: heart palpitations, anxiety, depression, irregular periods, sore/painful breasts, headaches, stress, acne, sugar cravings (only with clear capsules), poor memory, and fatigue.

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