



CLINICAL TRIAL STUDY SYNOPSIS:

CSC GEL (named Viacreme in the study)

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The study listed may include approved and non-approved formulations or treatment regimens. Data may differ from published or presented data and are a reflection of the limited information provided here. The results of a single trial need to be considered in the context of the totality of the available clinical research for a drug, device, or cosmetic product.

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|-----------------------------------|--|
| Title of Study: | Open label, single center study to assess efficacy and marketability of a topical personal care vaginal lubricant/moisturizer (labeled Viacreme) containing L-arginine and menthol |
| Investigator (s): | Kirstin LaVolette (Study Coordinator, FL) Ronald J. Thompson MD (Principal Investigator) |
| Study Center (s): | Central Florida, U.S.A. |
| Timing: | Study was completed in 2002 |
| First Observation | N/A- not time dependent |
| Final Report Package | N/A- not time dependent |
| Primary Objectives | To demonstrate the effectiveness of a topical personal care vaginal lubricant/moisturizer containing L-arginine and menthol; for increasing sexual satisfaction and determine validated marketing statements |
| Methodology (Study Design) | Single remote center, randomized, open label study of the test agent; 2 treatment groups with different application quantities to determine whether there is a meaningful difference between the use of 0.5 ml or 2.0 ml per application |
| Treatment Duration: | 8 Sexual Encounters |
| Dosage Regimen: | <p>The test agent is a topical personal care vaginal lubricant/moisturizer containing 2.0% L-arginine and 0.25% menthol. The base moisturizer/lubricant is substantially equivalent to lubricants already on the market.</p> <p>The menthol is included as a vasodilator and topical cooling/sensory agent in order to enhance absorption of the L-arginine. The L-arginine (a naturally occurring amino acid and a nutrient) is included as a substrate for nitric oxide synthase, which is known to increase local blood flow. A concentration of 2% L-arginine was selected as the highest concentration which was practical for the formulation. Since L-arginine is a naturally occurring amino acid and is present in the body in much larger quantities than in this topical cream, its inclusion in the formulation is not expected to be controversial and has been accepted by CDRH, US FDA.</p> |
| Treatment Groups: | <ul style="list-style-type: none"> • Group 1: 0.5 ml per sexual encounter • Group 2: 2.0 ml per sexual encounter |

| | |
|--|--|
| <p>Clinical Supplies & Data Collection Methods:</p> | <p>The study was coordinated and data was collected through an independent third-party, Kirsten LaValette. After responding to the radio advertisements, the coordinator screened, collected personal information (see study), and administered the pre-test over the telephone.</p> <p>Once a patient completed the consent process and met the inclusion and exclusion criteria, she was randomized to either the 0.5 ml usage group or the 2.0 ml usage group. Each participant was given (mailed) the product to be evaluated, either 2 or 8, 2 mL sachets (pillows).</p> <p>The study coordinator followed up with the participants intermittently, and ultimately administered the post-test by telephone after the participant had used the product during 8 separate sexual encounters. The patient questionnaires were then mailed to 40 J's LLC (James Thompson) for data decoding, data entry and analysis.</p> |
| <p>Test product, dose and mode of administration:</p> | <p>40 J's CSC Gel Formula, manufactured by an approved contract manufacturing vendor, 2 ml sachet pack, applied to the vagina and clitoris prior to sexual intercourse. 2 groups will be tested; Group 1 using 0.5 ml and Group 2 using 2.0 ml per sexual encounter.</p> |
| <p>Study Population</p> | |
| <p>Subject Characteristics:</p> | <p>Female subjects (20 to 57 years)</p> |
| <p>Number of Subjects:</p> | <p>83 women, enrolled at the single center</p> |
| <p>Number of Centers:</p> | <p>This will be a remote site study. No patient visits to a centralized monitoring facility are necessary.</p> |
| <p>Criteria for Inclusion</p> | <p>Women ages 18-60 (Average age 32.6 years)</p> |
| <p>Criteria for Exclusion</p> | <p>Pregnant women.</p> |

Criteria of evaluation:**Primary Efficacy:**

The primary objective was to determine whether or not the product produced a meaningful improvement in one or more of the following categories related to sexual function and responsiveness:

1. Lubrication: Time and Quality Measures
2. Orgasm Intensity
3. Orgasm Frequency
4. Time to achieve an Orgasm
5. Multiple Orgasms

In addition to the 5 categories, qualitative, open ended questions were asked to elicit personal responses on the products efficacy and marketability.

The qualitative questions focused on:

- Product Safety- “Did product cause any discomfort?”
- Partner’s Response- “What did partner think?”
- Suggestions- “...ways to make better?”
- Comments- “other comments about product?”

Secondary Efficacy:

None

Pharmacoeconomic and Quality of Life Measures

None

Concomitant Medications

Use and type of BC method shall be documented. Use and type of any other medications shall also be documented.

Safety Measures

Clinical adverse events collected at the completion of the study in the exit questionnaire.

Summary and Conclusions:*Primary Efficacy:*

Participants were their own controls for this study. Identical quantitative questions were asked pre and post product use to establish a baseline for the woman’s sexual level in the 5 categories, and then determine the effectiveness (improvement over baseline) as a result of product usage on these categories (as measured by the increase (or decrease depending on the question)). This format of having each woman as her own control was used because of the many differences of each woman’s personal preference and perception of sex. All data post use was acquired after a minimum of 8 uses. Overall initial data for the 0.5 ml and the 2.0 ml usage groups is pooled to determine overall product effectiveness. Data is then segregated and analyzed according to test group (0.5 ml vs 2.0 ml groups), and finally by age ranges (20-29, 30-39, 40+).

Lubrication Results:

n= number of women reporting:

Speed: Decrease in Time to Lubricate

Quality: Increase in Lubrication Quality Rating

Rating: Combo of both Speed and Quality

Table 1.1: Pooled Results

N=83

| Lubrication | n | % Reporting |
|--------------------|----|-------------|
| Speed | 66 | 79.7% |
| Quality | 57 | 68.8% |
| Rating | 71 | 85.6% |
| Uses to Max Effect | | 2.8 |

Table 1.2: Group Analysis

| N= | Group 1 (0.5ml) | | Group 2 (2.0ml) | |
|--------------------|-----------------|-------------|-----------------|-------------|
| | n= | % Reporting | n= | % Reporting |
| Lubrication: | | | | |
| Speed | 32 | 78.1% | 34 | 81.2% |
| Quality | 27 | 66.0% | 30 | 71.6% |
| Rating | 34 | 83.0% | 37 | 88.2% |
| Uses to Max Effect | | 2.58 | | 2.94 |

Table 1.3: Age Analysis (Groups Pooled)

| N= | Ages 20-29 | | Ages 30-39 | | Ages 40+ | |
|--------------------|------------|-------------|------------|-------------|----------|-------------|
| | n= | % Reporting | n= | % Reporting | n= | % Reporting |
| Lubrication: | | | | | | |
| Speed | 27 | 73.2% | 23 | 92.0% | 16 | 76.5% |
| Quality | 27 | 73.2% | 15 | 60.2% | 15 | 71.5% |
| Rating | 29 | 78.5% | 24 | 96.0% | 18 | 85.8% |
| Uses to Max Effect | | 3.08 | | 2.50 | | 2.52 |

Orgasm Rate Results:

n= number of women reporting improvement:

Aggregate: Increase in % of time they have an orgasm

Intercourse: Increase during Intercourse Only (Masturbation & Cunnilingus Included)

Table 2.1: Pooled Results

N=83

| Orgasm Percentage: | n | % Reporting |
|---------------------------|----------|--------------------|
| Aggregate | 53 | 64.2% |
| Intercourse | 31 | 37.2% |
| Masturbation | 33 | 39.8% |
| Cunnilingus | 23 | 27.6% |

Table 2.2: Group Analysis

| N= | Group 1 (0.5ml) | | Group 2 (2.0ml) | |
|---------------------------|------------------------|--------------------|------------------------|--------------------|
| | n= | % Reporting | n= | % Reporting |
| Orgasm Percentage: | | | | |
| Aggregate | 26 | 63.7% | 27 | 64.7% |
| Intercourse | 14 | 34.0% | 17 | 40.4% |
| Masturbation | 12 | 29.2% | 21 | 50.2% |
| Cunnilingus | 11 | 26.7% | 12 | 28.5% |

Table 2.3: Age Analysis (Groups Pooled)

| N= | Ages 20-29 | | Ages 30-39 | | Ages 40+ | |
|---------------------------|-------------------|--------------------|-------------------|--------------------|-----------------|--------------------|
| | n= | % Reporting | n= | % Reporting | n= | % Reporting |
| Orgasm Percentage: | | | | | | |
| Aggregate | 26 | 71.0% | 17 | 68.2% | 10 | 47.6% |
| Intercourse | 15 | 40.4% | 10 | 39.8% | 6 | 28.6% |
| Masturbation | 17 | 46.2% | 10 | 39.8% | 6 | 28.6% |
| Cunnilingus | 14 | 37.6% | 6 | 23.8% | 3 | 14.5% |

Time to Orgasm Results:

n= number of women reporting decrease in time to achieve an orgasm

Table 3.1: Pooled Results

N=83

| Orgasm Speed: | n | % Reporting |
|------------------------------------|----------|--------------------|
| Decrease in Time | 55.0 | 66.2% |
| Average Time(All) Min | | 3.05 |
| Average Time(Reported Dec.) | | 4.57 |

Table 3.2: Group Analysis

| N= | Group 1 (0.5ml) | | Group 2 (2.0ml) | |
|------------------------------------|------------------------|--------------------|------------------------|--------------------|
| | n= | % Reporting | n= | % Reporting |
| Orgasm Speed: | | | | |
| Decrease in Time | 26 | 63.4% | 29 | 69.0% |
| Average Time(All) Min | | 2.94 | | 3.15 |
| Average Time(Reported Dec.) | | 4.51 | | 4.62 |

Table 3.3: Age Analysis (Groups Pooled)

| | Ages 20-29 | | Ages 30-39 | | Ages 40+ | |
|------------------------------------|-------------------|-------------|-------------------|-------------|-----------------|-------------|
| N= | 37 | | 25 | | 21 | |
| Orgasm Speed: | n= | % Reporting | n= | % Reporting | n= | % Reporting |
| Decrease in Time | 28 | 75.6% | 14 | 56.0% | 13 | 61.9% |
| Average Time(All) Min | | 3.65 | | 2.70 | | 2.40 |
| Average Time(Reported Dec.) | | 5.03 | | 4.81 | | 3.46 |

Orgasm Intensity Results:

n= number of women reporting improvement:

Aggregate: Increase in orgasm intensity

Intercourse: Increase during Intercourse Only (Masturbation & Cunnilingus Included)

Table 4.1: Pooled Results

N=83

| Orgasm Intensity: | n | % Reporting |
|--------------------------|----------|--------------------|
| Aggregate | 61 | 73.5% |
| Intercourse | 34 | 41.0% |
| Masturbation | 50 | 60.2% |
| Cunnilingus | 25 | 30.1% |

Table 4.2: Group Analysis

| | Group 1 (0.5ml) | | Group 2 (2.0ml) | |
|--------------------------|------------------------|-------------|------------------------|-------------|
| N= | 41 | | 42 | |
| Orgasm Intensity: | n= | % Reporting | n= | % Reporting |
| Average | 29 | 70.7% | 32 | 76.2% |
| Intercourse | 13 | 31.7% | 21 | 50.0% |
| Masturbation | 26 | 63.4% | 24 | 57.1% |
| Cunnilingus | 11 | 26.8% | 14 | 33.4% |

Table 4.3: Age Analysis (Groups Pooled)

| | Ages 20-29 | | Ages 30-39 | | Ages 40+ | |
|--------------------------|-------------------|-------------|-------------------|-------------|-----------------|-------------|
| N= | 37 | | 25 | | 21 | |
| Orgasm Intensity: | n= | % Reporting | n= | % Reporting | n= | % Reporting |
| Average | 30 | 81.1% | 15 | 60.0% | 16 | 76.2% |
| Intercourse | 19 | 51.3% | 9 | 36.0% | 6 | 28.6% |
| Masturbation | 25 | 67.5% | 12 | 48.0% | 13 | 61.9% |
| Cunnilingus | 14 | 37.9% | 6 | 24.0% | 5 | 23.8% |

Multiple Orgasm Results:

n= number of women reporting:

Aggregate: Increase in % of time they have a multiple orgasm

Intercourse: Increase during Intercourse Only (Masturbation & Cunnilingus Included)

Table 5.1: Pooled Results

N=83

| Multiple Orgasm: | n | % Reporting |
|-------------------------|----------|--------------------|
| Total | 46 | 55.7% |
| Intercourse | 35 | 42.3% |
| Masturbation | 30 | 35.8% |
| Cunnilingus | 29 | 34.3% |

Table 5.2: Group Analysis

| N= | Group 1 (0.5ml) | | Group 2 (2.0ml) | |
|-------------------------|------------------------|--------------------|------------------------|--------------------|
| | n= | % Reporting | n= | % Reporting |
| Multiple Orgasm: | | | | |
| Total | 13 | 30.5% | 34 | 80.3% |
| Intercourse | 5 | 12.2% | 30 | 71.7% |
| Masturbation | 7 | 17.1% | 23 | 54.1% |
| Cunnilingus | 11 | 25.6% | 18 | 42.9% |

Table 5.3: Age Analysis (Groups Pooled)

| N= | Ages 20-29 | | Ages 30-39 | | Ages 40+ | |
|-------------------------|-------------------|--------------------|-------------------|--------------------|-----------------|--------------------|
| | n= | % Reporting | n= | % Reporting | n= | % Reporting |
| Multiple Orgasm: | | | | | | |
| Total | 18 | 49.3% | 20 | 80.0% | 8 | 38.1% |
| Intercourse | 13 | 34.4% | 14 | 57.5% | 8 | 38.1% |
| Masturbation | 5 | 14.5% | 16 | 65.5% | 8 | 38.1% |
| Cunnilingus | 8 | 22.0% | 12 | 49.5% | 8 | 38.1% |

Sampling of Open Ended Questions:

Q 9: What did your partner think of the product?

P064: "Enjoyed the sexual enhancement!" Age 28

P078: "Loved the masturbation part. Cooling feeling. Enjoyed the enhanced feeling."
Age 29

P032: "Partner was not too receptive, but I had multiple orgasms with self masturbation."
Age 24

Q 10: Do you have any suggestions to make the product better?

P066: "Bigger tube" Age 25

P036: "More and lots of it!! Great when kids aren't around." Age 38

Q 11: Do you have any other comments about the product?

P066: "...sexual experience was more intense." Age 25

P064: "Helped achieve having an orgasm w/ intercourse." Age 28

P042: "Helped w/achieving orgasm, but not having the desire to initiate sex." Age 32

Safety:

Q 8: Did the use of the product cause any discomfort? If yes, please explain.

A total of 14 women (16.9%) reported some type of irritation, stinging or discomfort, which was limited to the 1st couple of uses in many cases. All of the women continued the study and most reported positive results at the conclusion. The average age of women reporting the initial discomfort was 40.1 years, well above the 32.6 average ages of all participants. One participant in the 20-29 age group reported irritation (Group 1 & was on BCP), four participants in the 30-39 (one Group 1 & on BCP, two Group 2 no BCP, and one Group 1 no BCP) group reported irritation and 9 participants in the 40+ (all Group 1 no BCP) age group reported irritation.

Conclusions:*Overall Efficacy:*

Results obtained from the study showed an improvement in all of the categories. Approx 80 percent of women reported a decreased time to lubricate, 70 percent reported an increased lubrication quality and approx 85 percent had a positive lubrication score increase. Sixty-five percent of the women in the study reported increased orgasm occurrence, 66 percent percentage reported a decrease in time to achieve orgasm, 74 percent reported an increase in orgasm intensity and 56 percent reported an increase in multiple orgasm occurrence. The differences in efficacy between the test groups and age groups can be evaluated in the preceding tables.

Additional data analysis may be performed and published to analyze the impact of concomitant medications on the effectiveness, marketability and/or safety of the product in the two test groups.

Safety:

There were a small number of women reporting irritation; however that was attributed to stinging burning, and directly from the menthol in the formulation. There is evidence to suggest that older women should use more product per application to minimize the possibility of sensory irritation/burning.