



100% Natural Vaginal Lubricant Usage in Women With Gynecologic Cancer Receiving Irradiation

Chia Chia Sun¹ and Frances Wong²

1. Damiva Inc., Toronto, ON, Canada. 2. Radiation Oncology, BC Cancer Agency, Surrey, BC, Canada.

OBJECTIVE

Vaginal lubricants containing hyaluronic acid are indicated for menopausal vaginal dryness. The objective was to conduct a pilot to evaluate whether a completely natural vaginal lubricant containing hyaluronic acid (Mae by Damiva) is safe and effective in women with severely compromised vaginal health due to radiation therapy to treat gynecologic cancer. A secondary objective was to identify whether the natural vaginal lubricant could be used with a dilator.

BACKGROUND

Cancer of the vulva, vagina, uterine cervix and uterine corpus is routinely treated with external beam radiation and brachytherapy. Treatment methods often cause short-term inflammation, bleeding, soreness and irritation and long-term vaginal scarring and stenosis (narrowing). In extreme cases, the vaginal wall can fuse together and scar shut. Cancer patients are counselled to utilize a dilator (glass, plastic or rubber) to prevent the vaginal wall from becoming narrower and shorter. The vaginal tissue also becomes drier and less elastic, particularly if pelvic radiation has damaged the ovaries and induced menopause.

Up to 30% of young women receiving alkylating therapy and pelvic radiation have acute ovarian failure and therefore medically-induced early menopause (Ref 1: Childhood Cancer Survivor Study of 2,819 young females). Many gynecologic cancer patients are facing both induced menopause and cancer treatment at the same time, with accompanying psychological and physical distress. In addition, intercourse for gynecologic patients is often painful, a condition which can be long-lasting due to the long-term effects of radiation therapy.

Due to the long-lasting effects of radiation therapy, dilator usage is recommended indefinitely. The use of a dilator is often accompanied with an alcoholic gel that increases dryness. Our rationale was that a non-alcohol based product could be effectively used in this patient population to: 1) Promote efficacy in treating symptoms of vaginal dryness, 2) Prevent stenosis when used in combination with a dilator, and 3) Prevent dryness associated with using an alcohol-based gel.

This pilot study undertakes to understand the potential usage modalities and any safety issues in this severely compromised patient population before undertaking a larger clinical trial.

DESIGN

This non-interventional, open-label pilot trial was conducted at the BC Cancer Agency in British Columbia, Canada. The information was collected by survey in women treated for gynecologic cancer receiving irradiation. Women were provided with samples of natural lubricant and asked to complete a survey after usage. Women were informed that they could use the lubricant in advance of intercourse, with a dilator and/or for general vaginal comfort. The survey results were reviewed with a radiation oncologist during a follow-up meeting.

Figure 1: Sample Survey Question

Use of Lubricants and Dilators

Are you using a vaginal dilator after radiation therapy?

No Yes IF YES, please indicate how many times a week 0-1 2-3 4 or more

How are you using Mae by Damiva (check ALL that apply)?

Using Mae alone, without a dilator, for general comfort

Using Mae prior to intercourse

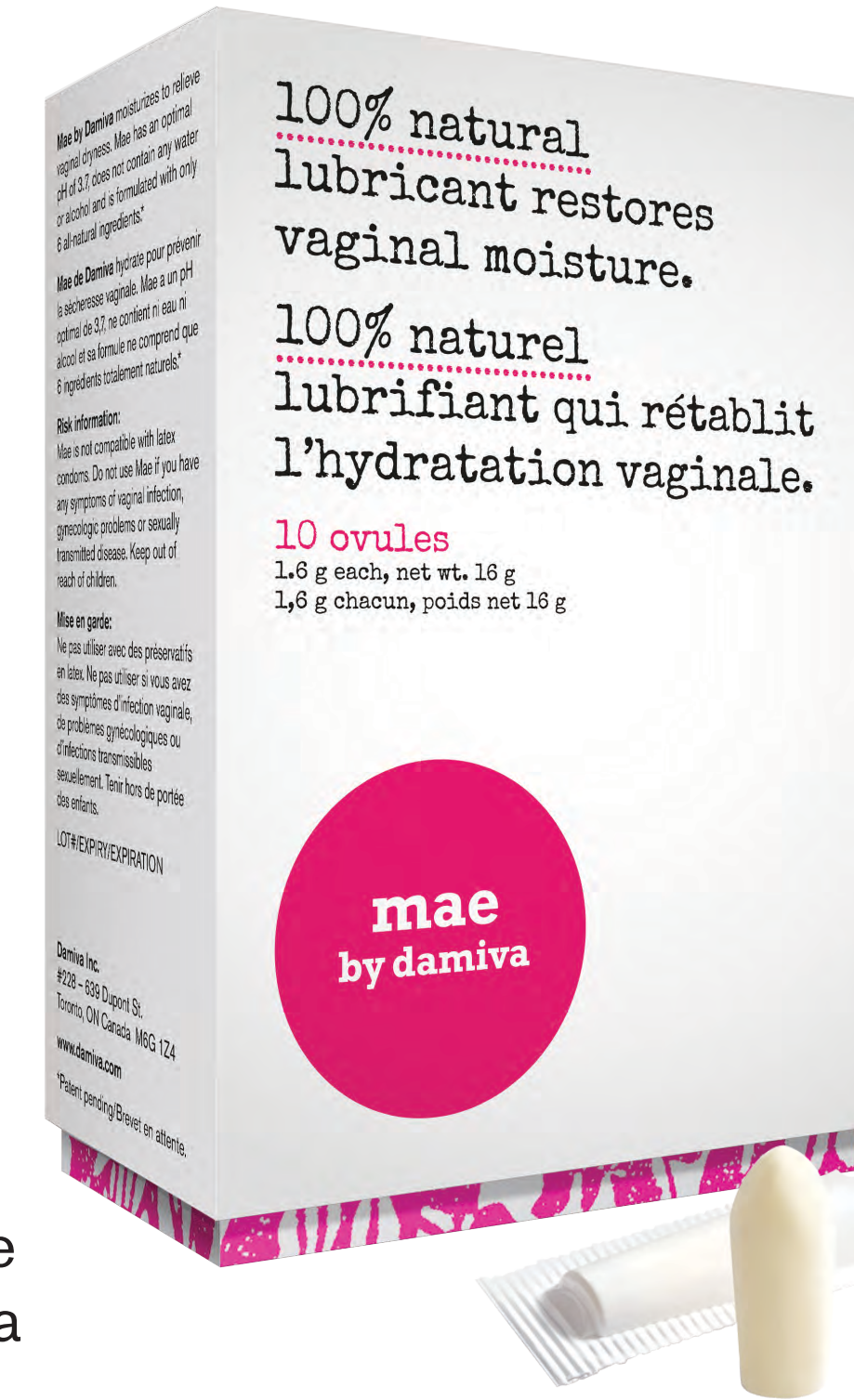
Using Mae after intercourse

Using Mae with a dilator, occasionally

Using Mae with a dilator, every time or almost every time

Other (please explain, for example using Mae every day)

Women used a 100% natural vaginal suppository that contains hyaluronic acid and is pH balanced to 3.7. Other suppository ingredients include cocoa butter, mangosteen butter, sea buckthorn extract, vitamin E and sucrose. Hyaluronic acid has been used in clinical trials to improve symptoms of vaginal atrophy (Ref 2).



Women were advised to use the suppository at their own discretion and without clinical intervention in order to better understand usage modalities. Any adverse events were self-recorded and followed up with a radiation oncologist.

RESULTS

We summarize the results of a pilot non-interventional, open-label study of use of a completely natural plant-based vaginal lubricant in eight (8) women who have received gynecologic radiation therapy in British Columbia, Canada, and were under the care of an oncologist. Out of eight women, seven completed the survey and utilized Mae. One woman did not use Mae as she found the suppository shell difficult to open and partially completed the survey.

The results of the trial indicate that all women who used the lubricant found at least one benefit of decrease in vaginal discomfort, improvement in intercourse comfort, improvement in ease of dilator insertion and increase in vaginal health and well-being.

Figure 2: Table of Benefits of Lubricant

Benefit	Patient #						
	1	2	3	4	5	6	7
Decreases general vaginal discomfort, e.g. itchiness or dryness	✓		✓	✓	✓		
Improves intercourse comfort	✓	✓	✓	✓		✓	✓
Improves ease of dilator insertion	✓		✓	✓			
Increases vaginal health and well-being	✓		✓	✓			✓

Four women found two or more benefits, three women benefitted in all areas (discomfort, intercourse, dilator usage and well-being), one woman found improved comfort with intercourse solely and another woman experienced decreased discomfort solely.

Out of seven women surveyed, six indicated they would use the natural lubricant again and one was unsure. Three of seven women were also using another vaginal product at the same time. The one woman who indicated “not sure” still received benefit, however, she was also using another product and had discomfort, not described nor elaborated.

Women were using the lubricant for different and multiple purposes. Six out of the 7 were using the lubricant for intercourse, one woman for both intercourse and dilator usage, one woman for general comfort and one woman used the lubricant only with a dilator.

Figure 3: Table of Usage Modalities

Usage Modality	Patient #						
	1	2	3	4	5	6	7
Alone, without a dilator, for general comfort					✓		
Prior to intercourse	✓	✓		✓		✓	✓
After intercourse							
With a dilator, occasionally							✓
With a dilator, every time or almost every time			✓				
Other							

Dosage schedules varied significantly between women. Two women used the lubricant less than once a month, three used it 1 to 4 times a month, one used it 5 to 8 times monthly and another woman used the product 9 to 15 times in a one month period.

The product is an ovule formed of plant butters. Women open and peel a plastic suppository shell, remove the ovule, and insert using fingers. Most women (five) rated the insertion as easy, one considered it mildly difficult and one found the application moderately difficult.

CONCLUSION

No adverse events were reported with usage of the natural lubricant. Despite the small sample number, we conclude that a natural lubricant appears to be safe and may be shown to provide benefit to women who have received radiation therapy after gynecologic cancer. The lubricant may also be utilized in conjunction with a dilator. Dilator usage helps prevent vaginal closure due to scarring after radiation therapy.

REFERENCES

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FOR MORE INFORMATION

Chia Chia Sun
CEO
Damiva Inc.
55 Avenue Rd. Suite 2400
Toronto ON M5R 3L2, Canada
416-884-3581
chiachia@mydamiva.com
Damiva.com