

Improving Women's Sexual Experience: Efficacy, Tolerability and Acceptability Evaluation of a New Non-Hormonal Intimate Gel (Libicare® Gel Íntimo)

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Abstract

Objective: Full and satisfying sexual life is an important factor for a good quality of life. The study objective was to evaluate the acceptability, efficacy and tolerability of "Libicare® Gel íntimo", a non-hormonal intimate vulvar gel for enhancing the sexual experience which is based on natural ingredients.

Methods: Healthy female volunteers aging 18 - 68 years and having 2 - 3 intercourse per week were included. After signing an informed consent, they applied the tested product on the external genital zone before the intercourse for 28 days. Volunteers completed questionnaires concerning both subjective efficacy and organoleptic characteristics of the tested product. Additionally, adverse events were reported and both dermatologist and gynecologist performed a visual evaluation of the skin of the experimental area after 4 weeks of application.

Results: A total of 21 volunteers were evaluated (mean age 33.95 years). Subjective efficacy: 90% or more of volunteers indicated that the product improves the sensory effects during the intercourse, relieves dryness and it is respectful with skin and easily removed. 67% and 81% reported climax acceleration and satisfaction with the suitability for using it with condom, respectively. None of the volunteers presented any alterations related with the product use. All volunteers were satisfied with the product in general and 90% or more were satisfied with the organoleptic characteristics.

Conclusion: Libicare® Intimate Gel shows very good subjective efficacy and excellent tolerability which met expectations of a good intimate gel for 100% the volunteers.

Keywords: Intimate Gel; Libicare; Sexual Experience; Non-Hormonal

Abbreviations

NO: Nitric oxide; NOS: Nitric Oxide Synthase; L-PCA: L-Pyrrolidone Carboxylic Acid

Introduction

It is largely recognized that sexual health can be a vital element in quality of life [1]. Social and cultural behaviors in addition to psychological and biological factors have affect the sexual understanding over a complex chemistry [2]. Therefore, to get a good understanding from sexual function, studying the relationship between this function and biological-psychological theories is significant. The ageing and routine as general, and in women, childbirth and the menopause would have the potential to root the sexual morbidity. Undoubtedly, any surgery to the urogenital system may affect sexual function [3]. Nowadays, biomedical attention in human sexuality has increased due to the social awareness on human sexual function [4-6].

Among biological factors, and, particularly, in women's sexual function, multiple systems take part, as it consists in a neurovascular process, controlled by psychological and hormonal inputs.

Respect to physiologic sexual stimulation, it mainly results in pelvic nerve-mediated genital smooth muscle relaxation, followed by an increase of arterial blood inflow into the external genital area. Due to this, female sexual arousal initiates and is maintained partly by a relaxation of the vaginal wall smooth muscle, which produces a lengthening and dilatation of the vagina [7,8]. In addition, since it is required a sufficient blood supply for a satisfying sexual experience, clitoral and vulvar vasodilatation occurs, as the enhancement of genital lubrication [9,10].

Beyond this complex physiological response, there is a personal and interpersonal importance of it. For instance, in case of orgasm, it has been seen that frequency and consistency of orgasms are positively associated with sexual satisfaction, which in turn is associated with relationship satisfaction [11], meaning that there is a need of comprehension of sexual satisfaction in relationships, understanding the attitudes and behaviors that enhance people's sexual lives.

Another important aspect of female sexual function is the time of menopause, a key symptom that is low sexual desire [12]. When symptoms like low sexual desire, interest or arousal are persistent and clinically significant, they are diagnosed as sexual dysfunctions that have to be treated since they affect negatively on the wellbeing and intimate relations; definitely, the whole sexual experience would become diminished [13].

Regardless of whether there is a disorder or just difficulties in sexual relationships, or even if what is wanted is simply to further improve the sexual experience, there is a general interest in helping to enhance this sexual satisfaction [14]. The use of stimulating gels for the intimate area in sexual relations is increasing to help make intercourse comfortable, pleasant and recover sensations that even allow prolonging the sexual act [15]. These enhancement products became more available and more attention should be paid on how men and women use them as part of their sexual experience. Therefore, a distinction between a product that provides hydration and comfort, and a product, which its composition also provides enhancement of sensory perception during intercourse, due to having an effect on the physiological sexual response, should be considered [16].

With the aim of making a product that provides not only the sense of lubricant but also helping in the physiological sexual response, a study with a newly developed non-hormonal intimate vulvar gel (*Libicare® Gel Íntimo*) based on natural ingredients - L-arginine, *Ginkgo biloba* leaf extract, Brazilian ginseng (*Pfaffia glomerata*) root extract with Arginine L-PCA, hyaluronic acid niosomes and a stimulating complex composed by *Panax Ginseng* root extract, B6 vitamin, Damiana (*Turnera diffusa*) extract and peppermint oil – was carried out.

Objective of the Study

The objective of this study was to evaluate the subjective efficacy, tolerability and acceptability of *Libicare® Gel Íntimo* to enhance woman's sexual experience during intercourse.

Materials and Methods

Healthy female volunteers aged 18 - 68 years having 2 - 3 intercourse per week were included. Each volunteer was informed before about the procedures of the study, signing an informed consent before starting. According to Spain regulations, ethical committee approval is not required for studies in volunteers with a non-drug and non-medical device product, which is already marketed and used within approved indication.

Volunteers presenting pathologies in the experimental area, relevant to dermatological pathologies (severe acne, atopic dermatitis, psoriasis, etc.) and those that had been subjected to a transplantation or extraction of organs or subjects with cranial trauma with current sequels were excluded. Besides, exclusion criteria contemplated those pregnant, breastfeeding or within a period of sexual activity without contraceptive medical treatment. Volunteers with cardiovascular, digestive, neurological, psychiatric, genital, urinary, hematological or endocrine progressive alteration, and immunodeficiency, were also excluded. The same for those with previous history of medicinal,

cosmetics, healthcare, industrial products (especially latex, aluminum or nickel) intolerance, previous history of allergies, photosensitivity or phototoxicity, with progressive cutaneous alteration or metabolic photodermatitis. Volunteers in antibiotic, antihistamine or corticosteroid treatment, as well as those with anti-acne treatment or applicants of other similar topical products in the experimental area during the study were also excluded.

Tested product

Libicare® Gel Íntimo is indicated to enhance the sexual experience and based on natural ingredients: L-arginine, *Ginkgo biloba* leaf extract, Brazilian ginseng (*Pfaffia glomerata*) root extract with Arginine L-PCA, hyaluronic acid niosomes and a stimulating complex composed by *Panax Ginseng* root extract, B6 vitamin, Damiana (*Turnera diffusa*) extract and peppermint oil.

Experimental procedure

After meeting all the inclusion/exclusion criteria and signed the informed consent, information about type of skin, consumption habits and preferences in habitual products for intercourse enhancement (frequency, efficacy and price) was collected from volunteers.

Volunteers were instructed in oral and written form about the frequency of use and the mode of application of the product, being asked not to use other product that they did not usually use during the study period. The product had to be applied on the external genital zone (intimate area) and spread before the intercourse for 28 days, and it could be used with or without condom. Volunteers were followed-up for 28 days.

Endpoint evaluation

Subjective efficacy

Volunteers completed a questionnaire concerning if the tested product favored intercourse, accelerated climax, improved sensory effects, relieved dryness, was respectful with skin, was easy to remove and suitable for use it with condom. A Likert scale of 5 points was used (5: strongly agree, 4: agree, 3: undecided, 2: disagree, 1: strongly disagree). Volunteers with opinions 4 and 5 were considered as satisfied.

Tolerability

There were also included questions relative to tolerability after the continued use of the product. In case any subject detected disagreeable symptoms, they filled a "Notification Form of Unwanted Effects" with the help of the specialists or researcher.

In addition, at the end of the study (day 28), a dermatologist and gynecologist performed a visual evaluation of the skin of the experimental area (intimate zone), evaluating the skin type and any adverse events volunteers could have had after product use.

Analyzed alterations were irritation/redness, inflammation, dryness, edema, among others, in a scale of 4 points (4: very slight, 3: slight, 2: moderate and 1: severe alteration), indicating if these alterations were related to the use of the product by using a 6-point scale (not related, unlikely, possible, likely, certain and not assessable).

Acceptability

At day 28, volunteers completed a questionnaire concerning organoleptic characteristics (general opinion, appearance, color, smell, texture, ease of application, comfortable packaging, ease of use, attractive packaging and resistance and suitability packaging) using a Likert-type scale of 7 points (7: I like it very much, 6: I like it moderately, 5: I like it slightly, 4: I neither like it nor dislike it, 3: I dislike it slightly, 2: I dislike it moderately, 1: I dislike it very much). Volunteers with opinions between 5 and 7 were considered as satisfied.

Results

Twenty-two female volunteers were initially included on the study. One woman abandoned the study voluntarily and specialists determined no further exclusion. Finally, subjective efficacy, tolerability and acceptability of the tested product were evaluated on 21 volunteers (mean age = 33.95 years) at the end of the study.

Baseline characteristics

Thirteen volunteers reported to have sensitive skin type while the remaining 8 had resistant type. Regarding whether using products

for enhancement of intercourse, 8 of them reported a habitual use, while 10 of them reported an occasional use, (remaining 3 did not use any product). The type of product used by these women were lubricants, some with heating effect, and one of them indicated using

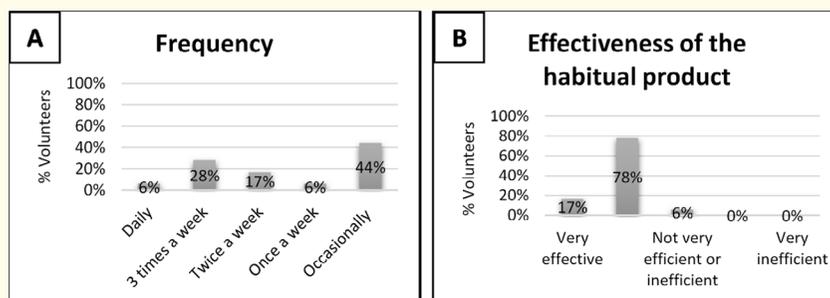


Figure 1: Preferences of volunteer's habitual products: (A) Frequency of use of habitual product reported by volunteers before starting the study. (B) Efficacy of the habitual product reported by volunteers before starting the study (N = 18).

rosehip oil. Preferences of volunteer’s habitual products are showed in figure 1.

Subjective efficacy

Volunteers were asked for whether the product favors intercourse, and 95% of women satisfied with that (Figure 2A). In addition, they were asked for whether the product accelerates climax, being the 67% of women satisfied with that (Figure 2B). Furthermore, 90% of volunteers indicated that the product improved the sensory effects during the intercourse. (Figure 2C). In case of relieving dryness, 96% of them were satisfied with this product’s property, too (Figure 2D). When they were asked if the tested product was respectful with their skin (Figure 2E), whether it was easily removed (Figure 2F), there were registered high levels of satisfaction. Then, in subjective evalua-

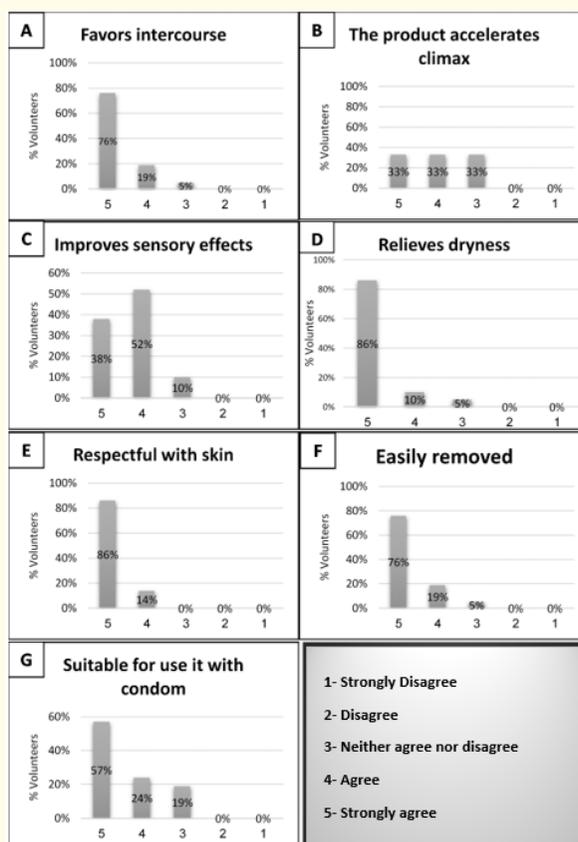


Figure 2: Subjective efficacy. Subjective evaluation by volunteers after 4 weeks about whether the product: (A) favors intercourse, (B) accelerates climax, (C) improves sensory effects, (D) relieves dryness, (E) was respectful with skin, (F) was easily removed and (G) was suitable for use with condom. Volunteers scoring 4 or 5 were considered satisfied. Relative frequency in scale level of agreement (N = 21).

tion, 81% of volunteers indicated satisfaction with the suitability of the tested product with condom (Figure 2G).

Tolerability evaluation

According to the clinical examination carried out by the dermatologist and the gynecologist, none of the volunteers presented any alterations related with the product use. According to the subjective evaluation of the product tolerability, none of the volunteers indicated undesirable symptoms during product use.

Acceptability: Global appreciation and organoleptic characteristics

Regarding subjective evaluation about acceptability, most of the volunteers were satisfied with the product (Figure 3): all of volunteers were satisfied with the product in general and all they thought that the product was fulfilling their expectations. Likewise, 100% of them were satisfied with product appearance and color, with easiness of use, with comfortable packaging, attractiveness and resistance of packaging and with ease of application. 90% of volunteers were satisfied with product smell, with suitability of packaging and with

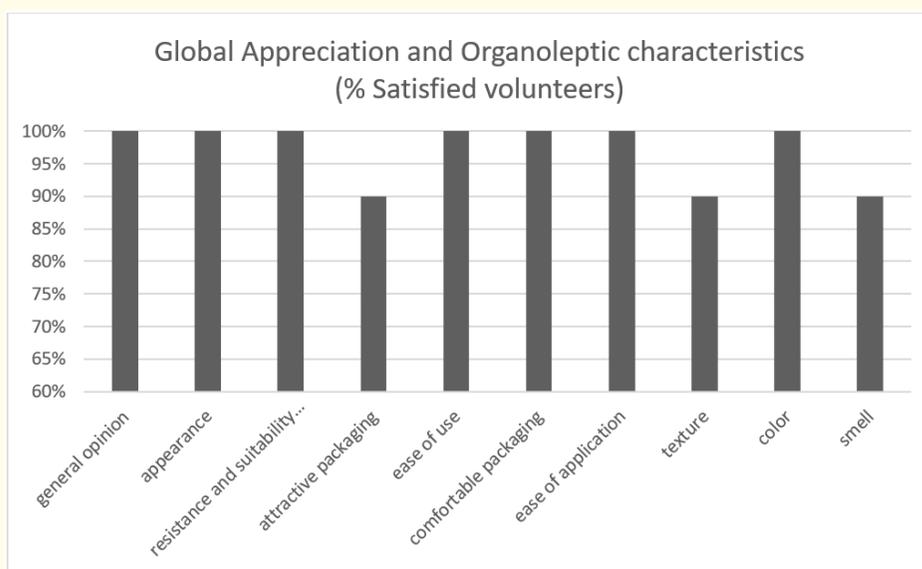


Figure 3: Percentage of volunteers satisfied with the product and its organoleptic characteristics (n = 21). Satisfied volunteers: scoring 5 - 7 in a Likert-type scale of 7 points (from 1: I dislike it very much to 7: I like it very much).

product texture.

Discussion

Results presented both dermatological and gynecological examination with the subjective evaluation by 21 female volunteers, reveal the good tolerability and effectiveness of the newly made *Libicare® Gel Íntimo*, a non-hormonal intimate vulvar gel for enhancing the sexual experience and based on natural ingredients.

When the subjective efficacy was evaluated, most of volunteers were satisfied. These results could be explained due to the effect of the ingredients of the gel, as its formulation is thought to help in the female physiological response. In addition, it is important to mention that the vast majority of female participating in this study already used products for sexual relations further supports these promising results in the efficacy of this intimate gel to improve sexual intercourse.

Focusing on the main ingredients, L-Arginine via topical is a precursor of nitric oxide (NO) synthesis by Nitric Oxide Synthase (NOS). NO synthesis is a key point in regulation of the NO/cGMP pathway, provides the final product, the synthesis of cGMP, which promotes the relaxation of vascular smooth muscle [17,18]. This blood vessels relaxation is essential for pleasure sensation, so, with arginine in the

tested gel composition, local sensitivity on genital tissues will be improved.

Another important ingredient in this newly released vulvar gel is a physio-vegetal complex made by the arginine salt of L-Pyrrolidone Carboxylic Acid (L-PCA) and sap of Brazilian ginseng (*Pfaffia glomerata*) roots. Brazilian ginseng is known to have antioxidant and anti-stress properties, such as increasing circulation among others [19]. Then, it has been seen that its combination with arginine L-PCA topically applied, has increased the cutaneous microcirculation in 11% of the women with circulation problems compared to placebo [20] and enhanced tactile perception, boosting sensorial pleasures of the skin.

Regarding the *Ginkgo biloba*, this plant is widely known due to its effectiveness in increasing circulation, as it is used in a wide range of circulation related problems [13]; so, it, increasing the irrigation to the application zone, helps to enhance the sexual response.

With the three components mentioned above, it could be explained the satisfaction of female volunteers when they used the gel for intercourse, in the 'favors intercourse' and 'improves the sensory effects' results on the subjective evaluation, as these ingredients help increase relaxation and microcirculation on the smooth muscle of the genital area. In this line of discussion, it could be explained also the fact that 67% of women considered the product to accelerate climax as it is able to increase perception of sensations during the intercourse.

When volunteers indicated that, the product was able to relieve dryness and to be respectful with skin, which could be explained, thanks to the hyaluronic acid-kaempferol in niosomal biotechnology effect. Niosomes are able to deliver an active substance prolonging the bioavailability. With this system, hyaluronic acid in the hydrophilic part of the niosome, and Kaempferol (inhibitor of hyaluronidase, an endogenous enzyme that degrades hyaluronic acid) in the outer layer, achieves a prolonged hydrating effect in the tissues, since it allows deep penetration of it. Therefore, with this biotechnology included in the gel's design, it allows the increment of tissues elasticity and a prolonged moisturizing effect, making the intercourse more comfortable [14].

At the end, the final combination of the tested product was made by numerous ingredients with stimulating properties that promote pleasurable comfort during intercourse; *Panax Ginseng* root extract, B₆ vitamin, Damiana (*Turnera diffusa*) extract and peppermint oil. It was tested as a topically applied gel before intercourse in men and women and showed an increase in the sexual appetite and a prolongation of the duration of the act [15]. This also can explain the satisfaction level of volunteers when evaluating the gel as it 'favors intercourse' and the 'improves sensory effects' too.

When the dermatologic and gynecologic examination has been performed, none of the volunteers presented any alterations related with the product use, as for the product tolerability, that none of them indicated undesirable symptoms during product use. This confirms the 'respectful with skin' property, among others, on the subjective evaluation by volunteers.

Limitations of the Study

Limitations of the study could be the inclusion of only healthy women, volunteers that were sexually functional and satisfied at the outset of the study, as it would be interesting to include those with unsatisfactory or some deficit in sexual life or even with some sexual dysfunction (complementing the corresponding treatment with the use of the intimate gel) and also include women using antidepressants or other medications known to influence blood flow/arousal.

Conclusions

The non-hormonal intimate vulvar gel, *Libicare® Gel Íntimo*, shows very good subjective efficacy to help intercourse being comfortable, pleasant and to recover sensations that even allow prolonging the sexual act, in healthy women with satisfactory sexual life. Likewise, *Libicare® Gel Íntimo* is dermatological and gynecologically very well tolerated, and also its organoleptic characteristics were very well accepted for participants. As consequence, under the conditions of this study, the product met the expectations of a good sexual enhancing gel for 100% of the volunteers, which would be willing to use it.

These results in healthy and sexually satisfied women show that there is a need to explore new forms of treatment to go further simple lubrication by looking for natural products that combine it with actions on the physiological sexual response, that is, to increase circulation, sensitivity and tactile perception, trying to achieve greater arousal, and, as seen in this study, that even accelerate the climax. Because

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