

Julva® Pro, a superior treatment option for vaginal atrophy and menopause symptoms in women

Dr. Anna Cabeca

With aging, menopause, and hormonal changes some **75%** of post-menopausal women suffer from vaginal atrophy¹ which can include,

- vulvar-vaginal thinning and irritation
- painful intercourse due to excessive vaginal dryness
- increased vaginal and bladder infections (due to decreased normal flora, loss of lactobacilli and increased pH)
- leaking urine
- increased skin disorders affecting the urogenital tract (vulvodynia, vestibulitis, hypertrophic dystrophy, dermatitis)
- decreased desire, arousal and orgasm
- pelvic prolapse symptoms such as pressure and trouble eliminating

Younger women can experience these symptoms as well.

This white paper will discuss the many vaginal atrophy symptoms women experience naturally with aging, and will present a comparison of current treatment options. The author will also discuss a less well known and often overlooked option – the use of the natural hormone DHEA - for effectively treating a more comprehensive range of vaginal atrophy symptoms.

The paper will present scientific research and clinical findings relating to the author's preferred vaginal atrophy treatment method, **non-prescription topical DHEA cream**.

Natural aging erodes the health and integrity of the vaginal lining

Before menopause a woman's ovaries produce many of her sex hormones including estrogen. This female hormone maintains the health and integrity of the vaginal lining. During peri-post menopause, women experience declining hormone levels including estrogen, progesterone, testosterone and dehydroepiandrosterone (DHEA).

Women's ovaries gradually decrease producing these hormones causing vaginal lining shrinkage and drying due to decreased healthy secretions. Muscle loss also occurs. The lining becomes less elastic and thin, causing irritation and discomfort. The ovaries predominantly stop producing estrogen after menopause.

These and the other symptoms women experience from these decreasing hormones are life affecting.

¹ Fernand Labrie, MD, PhD, David Archer, MD, Céline Bouchard, MD, et al. Intravaginal dehydroepiandrosterone (Prasterone), a physiological and highly efficient treatment of vaginal atrophy. *The Journal of the North American Menopause Society*. 2009;16(5):907-922.

Stress urinary incontinence (SUI), the involuntary leakage of urine, has been estimated to affect over **50%** of women between the ages of 20 to 80 years, and was reported at **47%** in a younger group consisting of women between 20 and 49 years of age.² Some estimates of women affected are considerably higher.

Many women increasingly wear protection in the form of pads or incontinence underwear for everyday activities. Even television advertising now includes a number of ads for these products and the adult incontinence category of new products has been booming.

Women may suffer from a decreased libido. The decline in androgens such as testosterone and DHEA are particularly associated with diminishing libido.^{3 4}

Increased pain during intercourse, increased post coital infections and the decreased libido associated with vaginal atrophy has also been shown to increase the level of overall sexual distress in women. Sexual distress has been associated with a higher incidence of depression and relationship conflicts^{5, 6} with more than **40%** of women in the United States reporting sexual problems.⁷

Yet only **20% to 25%** of symptomatic women having vaginal atrophy seek medical treatment.⁸

Lack of reporting symptoms to a doctor can be due to embarrassment, and/or a lack of awareness of vaginal health or treatment options. Women cannot readily examine their vulva or vagina, and can't see the tissue changes that are otherwise easily visible to a physician. A physician can see extreme tissue changes in terms of color (pale or red), dryness, thinning and irritation (red or raw patches).

Women may also mistake their symptoms for common irritations, allergies or infections. More often the changes are so gradual, that the symptoms go unnoticed until there is pain, discharge, or incontinence.

The current life expectancy for American women is greater than 80 years old (as benchmarked in 2010 census data) and continues to increase. Given the average age of menopause onset is 50.5 years, it is estimated that women may expect to live almost **40%** of their entire lives after menopause in this discomfort and decreased quality of life.⁹

² Patrick J. Culligan, MD, and Michael Heit, MD, University of Louisville Health Sciences Center, Louisville, Kentucky. Urinary incontinence in women: evaluation and management. *Am Fam Physician*. 2000; Dec 1;62(11):2433-2444.

³ S. Leiblum, G. Bachmann, E. Kemmann, D. Colburn, L. Schwartzman. Vaginal atrophy in the postmenopausal woman. The importance of sexual activity and hormones. *JAMA*. 1983;249(16):2195-2198. hormones.

⁴ N.E. Avis, S. Brockwell, J.F. Randolph Jr, et al. Longitudinal changes in sexual functioning as women transition through menopause: results from the Study of Women's Health Across the Nation. *Menopause*. 2009;16(3):442-452.

⁵ L. Dennerstein, J.R. Guthrie, R.D. Hayes, L.R. DeRogatis, P. Lehert. Sexual function, dysfunction, and sexual distress in a prospective, population based sample of mid-aged, Australian-born women. *J Sex Med*. 2008 Oct;5(10):2291-9. Epub 2008 Jul 14.

⁶ L.R. Knoepp, S.H. Shippey, C.C. Chen, G.W. Cundiff, L.R. DeRogatis, V.L. Handa. Sexual complaints, pelvic floor symptoms, and sexual distress in women over forty. *J Sex Med*. 2010 Nov;7(11):3675-82.

⁷ Jan L. Shifren, MD; Brigitta U. Monz, MD; Patricia A. Russo, PhD; Anthony Segreti, PhD; Catherine B. Johannes, PhD. Sexual problems and distress in United States women: prevalence and correlates. *Obstetrics & Gynecology*. 2008 November;112(5):970-978.

⁸ Fernand Labrie, MD, PhD, David Archer, MD, Ce'line Bouchard, MD, et al. Intravaginal dehydroepiandrosterone (Prasterone), a physiological and highly efficient treatment of vaginal atrophy. *The Journal of the North American Menopause Society*. 2009;16(5):907-922.

⁹ Sharon J. Parish, Rossella E. Nappi, Michael L. Krychman, et al. Impact of vulvovaginal health on postmenopausal women: a review of surveys on symptoms of vulvovaginal atrophy. *Int J Womens Health*. 2013;5:437-447.

Unlike hot flashes which usually end even without treatment, vaginal atrophy symptoms usually increase in severity over time.¹⁰

Decreasing hormones are also an important clinical health issue beyond vaginal health. Hot flashes, bone loss, fat accumulation, loss of muscle mass and strength¹¹, memory loss, cardiovascular disease, and type 2 Diabetes are additional concerns.¹²

Current treatment options are ineffective

Traditional treatment options for vulvar-vaginal atrophy are only partially effective in addressing the many symptoms. Additionally there are known safety risks.

Treatment for vulvar-vaginal irritation and pelvic support issues has been traditionally limited to lubricating creams and OTC options, herbal therapies, estrogen therapies and other prescriptions, Kegel/pelvic-strengthening exercise and surgery.

Lubricants and vaginal moisturizing creams

While helpful for lubrication these products are primarily cosmetic and do not treat underlying concerns. They may help with irritation and painful intercourse due to reducing dryness.

- **Water-based lubricants** include: K-YJelly, FemGlide, Summer's Eve and others, and are non-staining. Silicone-based lubricants include Pink, Pure Pleasure and others.
- **Oil-based lubricants** include using mineral oil, petroleum jelly or baby oil. These are not recommended as they can actually cause irritation and have also been associated with high rates of latex condom breakage.
- **Vaginal moisturizers** include Replens, Moist Again, K-Y Liquibeads and products containing hyaluronic acid (Hyalo Gyn and Revaree).

Natural solutions such as organic coconut oil, Ayurveda ghee (combined with herbs) and Yes (an OTC organic lubricant) are also available and do not contain the additional chemicals that can be seen in many commercial lubricant and vaginal moisturizing solutions.

Herbal therapies

A number of OTC herbal remedies are available containing black cohosh, soy isoflavones, magnolia bark and other ingredients.

Black cohosh has been shown in some studies to address hot flash and night sweat symptoms, but additional studies are needed. The *American College of Obstetricians and Gynecologists (ACOG)* reports a concern that many of the early studies were poorly designed and did not evaluate the safety and effectiveness of black cohosh beyond 6 months of use.¹³

¹⁰ J. Calleja-Agius, M.P. Brincat. Urogenital atrophy, *Climacteric*. 12 (4) (2009) 279–285.

¹¹ Labrie F, Diamond P, Cusan L, Gomez JL, Be' langer A, Candas B. Effect of 12-month dehydroepiandrosterone replacement therapy on bone, vagina, and endometrium in postmenopausal women. *J Clin Endocrinol Metab*. 1997;82:3498-3505.

¹² DT Villareal, JO Holloszy. Effect of DHEA on abdominal fat and insulin action in elderly women and men: a randomized controlled trial. *JAMA* 2004;292:2243-2248.

¹³ Available at: <http://umm.edu/health/medical/altmed/herb/black-cohosh>. Accessed January 2, 2017.

In 2003 one study showed that a soy-rich diet was shown to increase the maturation indices of vaginal cells and deemed an effective preventive intervention against menopausal effects and vaginal atrophy, but more research is needed.¹⁴

Some products available in the market are Estroven and Remifemin.

Soy products may not be appropriate for women having breast cancer. Soy products may contain soy that has been genetically modified. My greatest concern with soy is the majority of our sources are GMO; so I have advised women in only using non-GMO fermented soy foods such as miso or tempeh in moderation.

Here is a chart summarizing the above treatment options:

Comparison of Treatments for Vaginal Atrophy
(1 of 3 charts)

	Addresses Thinning	Improves Dryness & Irritation	Reduces Pain During Intercourse	Addresses Leaking Urine	Improves Prolapse Symptoms	Improves Libido & Satisfaction	Addresses hot flashes	Contraindications
Lubricants & Vaginal Moisturizing Creams								
Water-based lubricants	No	Yes (temp)	Possibly (reduces dryness)	No	No	Possibly (less pain)	No	Added chemicals
Silicon-based lubricants	No	Yes (temp)	Possibly (reduces dryness)	No	No	Possibly less pain)	No	Added Chemicals
Oil-based lubricants (mineral oil, petrol jelly, baby oil)	No	Yes (temp)	Possibly (reduces dryness)	No	No	Possibly (less pain)	No	Added Chemicals; latex condom breakage.
Vaginal moisturizers	No	Yes (temp)	Possibly (reduces dryness)	No	No	Possibly (less pain)	No	Added Chemicals
Natural solutions (organic coconut oil, Ayurvedic ghee with herbs, Yes)	No	Yes (temp)	Possibly (reduces dryness)	No	No	Possibly (less pain)	No	
Herbal Remedies								
Black cohosh, soy isoflavones, magnolia bark	No	Possibly (soy)	No	No	No	No	Possibly hot flashes and night sweats (Black cohosh)	Soy not recommended for women with breast cancer; products may contain GMO.

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Estrogen therapies

Low-dose vaginal estrogen therapy

Predominant medical therapy of vaginal dryness and pain has been with vaginal estrogen.

This therapy can be prescribed as vaginal tablets, creams or rings. These are delivered locally within the vagina and therefore minimize estrogen increases in blood levels along with related possible side effects. They help improve the thickness and elasticity of the vaginal lining but do not affect the deeper tissue or supporting muscles, nor does research show that they address incontinence issues.

¹⁴ L.M. Chiechj, G. Putignano, V. Guerra, M.P Schiavelli, A.M. Cisternino, C. Carriero. The effect of a soy rich diet on the vaginal epithelium in postmenopause: a randomized double blind trial. *Mauritas*. 2003. Aug 20;45(4):241-6.

Anecdotal feedback from some women using these products has raised the question as to whether they help some individuals with incontinence issues, but research is required to validate this question further. Manufacturers of these prescription-only products advertise that they help with dryness, pain during intercourse and painful urination.

Rather than just temporarily adding moisture (like the above lubricants) they actually work to reverse the thinning and dryness of vaginal tissue; these effects may help with painful sexual intercourse. These products have not been found to improve libido.

Examples include the prescriptions: Vagifem, Premarin, Estrin and Estrace.

Due to the estrogen content, vaginal estrogen therapy is not recommended for some women. Women with breast cancer or women with a history of stroke or heart attack, blood clots or liver disease should not opt for estrogen replacement therapies.¹⁵

Hormone replacement therapy (HRT) and vaginal health

Estrogen products, alone or in combination, that raise levels of the hormone throughout the body (systemically), not just in the vagina, are referred to as “hormone replacement therapy (HRT)”. These products address vaginal atrophy and related pain during sex in postmenopausal women as well as addressing other common symptoms of menopause such as hot flashes and night sweats.

Despite their benefits on vasomotor symptoms, **40%** of women receiving systemic estrogen therapy have persistent vaginal symptoms.¹⁶ Often local estrogen treatment is preferred unless hot flashes are the major issue. Estrogen however, addresses only the mucosal layer of the vaginal tissue.

Studies have shown controversially that postmenopausal women do not benefit from oral hormone therapy for treatment of urinary incontinence. Some studies conclude that HRT has been associated with worsening urinary incontinence.¹⁷

HRT, typically not bio-identical including estrogen and progestins (differs from bio-identical progesterone) is not known to address libido although pain during sexual intercourse may be diminished.

HRT therapy has been shown to help prevent osteoporosis.¹⁸

Hormone replacement therapy prescriptions may contain estrogen alone or may include progestogen (synthetic progesterone) along with estrogen. There are known risks relating to increased risk of blood clots, breast cancer, heart attack and stroke with oral administration.

It is this author’s preference from clinical and scientific experience and research that hormone replacement should only be bio-identical and in the lowest effective dose initially to achieve optimal results.

Kegel/pelvic floor strengthening exercises

¹⁵ Rippey L, Marsden J. Is HRT justified for symptom management in women at higher risk of developing breast cancer? *Climacteric*. 2006;9:404–15.

¹⁶ S.L. Johnston, S.A. Farrell, C. Bouchard, et al. The detection and management of vaginal atrophy. *J Obstet Gynaecol Can* 2004;26:503-515.

¹⁷ Jay H. Lee, MD, Suzanne Gomez, MD, Terry Ann Jankowski, MLS. Hormone therapy for postmenopausal women with urinary incontinence. *Am Fam Physician*. 2011 Jul 1;84(1).

¹⁸ LP Shulman. Transdermal hormone therapy and bone health. *Clin Interv Aging*. 2008;3:51–4.

Kegel exercises strengthen the pubococcygeus muscle and can improve symptoms of incontinence, as well as arousal and orgasm. They can also prevent or improve symptoms of pelvic organ prolapse, in which the uterus or bladder bulge into the vagina due predominantly to muscle weakness.

- Kegel exercises involve contracting and relaxing the muscles of your pelvic floor, which holds your uterus and bladder above your vagina. Learn to do Kegels correctly at: <https://youtu.be/2erHStClk2g>
- Women can also use jade balls/lelo balls/kegel balls
- It is also important to avoid exercises that cause increased pressure to the pelvic floor.

Here is a summary of the estrogen treatment options, as well as the pelvic floor health (Kegels) options:

	Addresses Thinning	Improves Dryness & Irritation	Reduces Pain During Intercourse	Addresses Leaking Urine	Improves Prolapse Symptoms	Improves Libido & Satisfaction	Addresses hot flashes	Contraindications
Low Dose Vaginal Estrogen Therapy								
Locally applied estrogen in tablets, creams or rings	Yes	Yes (reverses dryness)	Yes	Possibly	Possibly	Possibly (less pain)	No	Prescription Only. Breast cancer concerns.
HRT (Hormone Replacement Therapy)								
Use of estrogen alone or in combination with synthetic progesterone (progestogen)	Possibly	Possibly	Possibly	No. Some studies suggest urinary incontinence can worsen.	No	Possibly (less pain)	Addresses hot flashes and night sweats.	Prescription Only. Breast cancer concerns. The author prefers the use of bio-identical hormones at the lowest effective dose
Kegel/Pelvic floor exercises								
Kegel and pelvic floor exercises to increase pelvic floor strength.	No	No	No	Yes	Yes	Yes	No	Exercises must be done correctly.

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Surgical options

Surgical options have traditionally included specific surgeries focused on vulvar rejuvenation as well as those to support pelvic support and incontinence issues. These are currently viewed as two different categories of surgical intervention, one for functional health reasons (incontinence and prolapse) and one viewed primarily as cosmetic.

1. Labiaplasty and vaginoplasty viewed as primarily cosmetic.

Many women view these procedures as important for their self-esteem and sexual satisfaction. However, most mainstream health organizations still consider them as cosmetic.

American Society of Aesthetic Plastic Surgery (ASAPS) released statistics in 2014 that revealed a **49%** increase (from 5,070 surgeries to 7,535) in labiaplasty and other genital cosmetic procedures.¹⁹ A detailed review of these procedures can be found at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3312147/>.

The *American Congress of Obstetricians and Gynecologists* have stated in 2007, and reaffirmed in 2014²⁰ that,

“So-called "vaginal rejuvenation," "designer vaginoplasty," "revirgination," and "G-spot amplification" are vaginal surgical procedures being offered by some practitioners. These procedures are not medically indicated, and the safety and effectiveness of these procedures have not been documented. Clinicians who receive requests from patients for such procedures should discuss with the patient the reason for her request and perform an evaluation for any physical signs or symptoms that may indicate the need for surgical intervention. Women should be informed about the lack of data supporting the efficacy of these procedures and their potential complications, including infection, altered sensation, dyspareunia, adhesions, and scarring.”

G-shot injection

This is the injection of collagen or Hyaluronic acid injected into the G spot. **87%** of recipients in one pilot study reported increased sexual arousal and gratification.²¹

Pelvic Support and Incontinence Surgery viewed as addressing functional and urinary incontinence issues.

Laser therapy (such as the MonaLisa Touch)

Vaginal laser treatment was approved by the *U.S. Food and Drug Administration (FDA)* for aesthetic use in 2014, including approval for “gynecologic use”.²²

In research, the laser technology has been found to result in tissue regeneration and to address several symptoms relating to vaginal atrophy. In particular the vaginal mucosa tissue becomes more nourished and hydrated; the epithelium becomes thicker and regains some elasticity. It also reestablishes a more acidic vaginal pH.

Note, however, that while approved for “gynecologic use” vaginal laser therapy is not FDA approved for the specific purposes of treating vaginal atrophy, including vaginal dryness, pain during intercourse, incontinence, pelvic prolapse, low libido or other symptoms. Physicians offer these treatments off-label when addressing vaginal atrophy symptoms. The procedure is not normally covered by insurance and can be expensive.

¹⁹ Available at: <http://asj.oxfordjournals.org/genitalrejuvenation>. Accessed January 2, 2017.

²⁰ Available at: <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Vaginal-Rejuvenation-and-Cosmetic-Vaginal-Procedure>. Accessed January 2, 2017.

²¹ Available at: www.thegshot.com. Accessed January 2, 2017.

²² Available at: <https://www.acog.org/-/media/434ADADB30E846B09D359F3F1432510E.pdf>
Fractional laser treatment of vulvovaginal atrophy and U.S. Food and Drug Administration clearance position statement The American College of Obstetricians and Gynecologists and The American Congress of Obstetricians and Gynecologists. May 2016. Accessed January 2, 2017.

There are different thermal laser therapies (CO₂-based and Er: YAG-based) and also radio frequency-based laser treatments. CO₂ lasers like the MonaLisa Touch are considered fractional lasers and research showing positive benefits with vaginal atrophy symptoms has been done primarily using these types of lasers. Although initial research appears to indicate laser treatment is safe longer term follow-up studies are warranted.

Pelvic prolapse and incontinence surgeries

Research prior to 2014 has shown that about **3%** of U.S. women will have symptoms of prolapse in a given year. According to the authors of one study published in 2014, in the *Journal of the American Medical Association*, about 300,000 U.S. women undergo surgery for prolapse every year.²³

The two most common surgeries are uterosacral ligament suspension and sacrospinous ligament fixation. This study, partly funded by the *National Institute of Health Office of Research on Women's Health*, found positive outcomes for both treatments relating to prolapse symptoms and a small risk of side effects. The same authors suggest that by the year 2050, 44 million women in the U.S. will be facing symptoms of pelvic prolapse or pelvic floor disorders.

While these procedures may address pelvic prolapse and incontinence issues they do not address many of the other major symptoms of vaginal atrophy including dryness and itching, pain with intercourse or libido/sexual satisfaction.

Non Traditional Treatment Options include SERMs and DHEA

Less known hormone therapy treatment options include **selective estrogen receptor modulators (SERMs)** and the use of DHEA.

SERMs

Women suffering from vaginal atrophy may utilize prescription-based SERMs, rather than traditional estrogen therapies, for relief. SERMs block or activate the estrogen receptors in certain areas of the body and not others. This can make them safer than estrogen therapy alone especially in a woman having a history or family history of breast cancer. SERMs can also relieve other menopausal symptoms such as hot flashes and even bone density.

SERMS are unique to different parts of the body, so a SERM can block estrogen's negative action in breast cells while activating positive effects in other cells, such as bone and uterine cells.

SERMS with positive vulvar-vaginal effects include lasofoxifene and ospemifene. These SERMs improve vaginal atrophy and reduce vaginal pH and more, but do have potentially serious side effects (including increased risk for blood clots, stroke and heart attack; along with other less serious yet common side effects such as headaches and vaginal bleeding...be sure to discuss with your prescribing doctor).²⁴ More research is ongoing.

²³ Barber, M. D., L. Brubaker, K.L. Burgio, H.E. Richter, I. Nygaard, S.F. Meikle; *Eunice Kennedy Shriver National Institute of Child Health and Human Development Pelvic Floor Disorders Network* (2014). Comparison of two transvaginal surgical approaches and perioperative behavioral therapy for apical vaginal prolapse: the OPTIMAL randomized trial. *JAMA*, 311(10), 1023–1034.

²⁴ J.V. Pinkerton, F.Z. Stanczyk. Clinical effects of selective estrogen receptor modulators on vulvar and vaginal atrophy. *Menopause*. 2014 Mar;21(3):309-19.

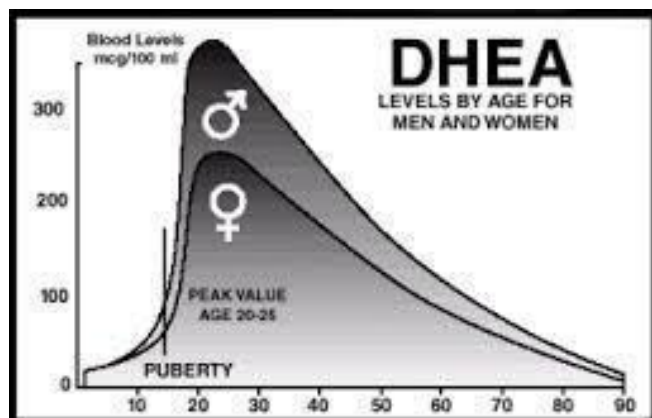
DHEA – The perfect natural solution

While most research and available treatments have been focused on the effects of diminishing estrogen and testosterone, there is another key hormone that has been found to play an important role in addressing vaginal atrophy symptoms, and that is dehydroepiandrosterone (DHEA).

DHEA is an androgen, like testosterone. Androgens are important to the integrity of skin, muscle, and bone (in both males and females) and have a role in maintaining libido. They also improve energy level and mental alertness, provide cardiovascular protection by lowering cholesterol, and enhance bone building (by increasing calcium retention).

DHEA originates from the adrenal gland. It is an inactive precursor which leads to the production of active sex hormones like androgens or estrogens in specific cells and tissues. As estrogen levels naturally decrease it is DHEA that continues to be a remaining source of estrogens and androgens in the woman's body.

DHEA produced by the body naturally “extends” protective benefits to women as their estrogen levels decrease, but only for a time. There is a progressive decrease in serum DHEA which starts at the age of 30 years with an average **60%** loss observed by menopause.²⁵



Natural decline of DHEA

DHEA, however, can be introduced and utilized by the body. DHEA can be introduced orally or locally (vaginally or through topical application around the vulva).

Oral DHEA

While used for a variety of other health benefits, Oral DHEA has not been shown to address vaginal atrophy symptoms.²⁶

²⁵ Labrie F, Belanger A, Cusan L, Gomez JL, Candas B. Marked decline in serum concentrations of adrenal C19 sex steroid precursors and conjugated androgen metabolites during aging. *J Clin Endocrinol Metab* 1997;82:2396-2402.

²⁶ R.M. Goel, A.R. Cappola. Dehydroepiandrosterone sulfate and postmenopausal women. *Curr Opin Endocrinol Diabetes Obes*. 2011 Jun;18(3):171-6.

Locally Applied DHEA

Topical DHEA has been found to have favorable effects on skin health and appearance²⁷ due to the production of collagen.

If DHEA is delivered directly to the vagina, the tissues transform DHEA to the estrogen, estradiol.²⁸ This natural production of estradiol occurs without a significant release of estrogens systemically in the blood.

The author and other physicians have been able to write prescriptions for customized vaginal and topical DHEA and other hormones for decades with positive results.

In November 2016 the U.S. Food and Drug Administration (FDA) approved the first product containing the active ingredient **Prasterone**, also known as DHEA.²⁹ The product, **Intrarosa®**, was approved to treat women experiencing moderate to severe pain during sexual intercourse, a chief symptom of vulvar atrophy.

Here is a summary of surgical options, SERMS and DHEA.

	Addresses Thinning	Improves Dryness & Irritation	Reduces Pain During Intercourse	Addresses Leaking Urine	Improves Prolapse Symptoms	Improves Libido & Satisfaction	Addresses hot flashes	Contraindications
Vaginal Surgeries								
Labiaplasty and vaginoplasty	No	No	No	No	No	Possibly - increases self-esteem	No	Viewed as cosmetic in nature
G-Shot injection - injection of collagen or Hyaluronic acid	No	No	No	No	No	Yes	No	Viewed as cosmetic
Mona Lisa Touch Laser	Yes	Yes	Possibly (reverses dryness)	No	No	Possibly (less pain)	More acidic vaginal pH.	Is expensive and may not be covered by insurance.
Pelvic Support and Incontinence surgery	No	No	No	Yes	Yes	No	No	
SERMS								
SERMs block or activate the estrogen receptors in certain areas of the body and not others.	Yes	Yes	Yes (reduces dryness)	No	No	Possibly (less pain)	More acidic vaginal pH. May reduce hot flashes.	Prescription Only. Many known potential side effects.
A Newer Proven Approach - DHEA								
Vaginal DHEA tablet	Yes	Yes	Yes (reverses dryness)	Yes	Yes	Yes	More acidic vaginal pH.	Prescription Only. One FDA approved drug for pain reduction only.
OTC vulvar DHEA cream (Julva)	Yes	Yes	Yes (reverses dryness)	Yes	Yes	Yes	More acidic vaginal pH.	Over the counter. No FDA review required. Available at Julva.com

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²⁷ Available at:

<http://www.lifeextension.com/magazine/2010/12/new-research-substantiates-the-anti-aging-properties-of-dhea/page-02>. Accessed January 2, 2017.

²⁸ Labrie F, Bélanger A, Bélanger P, et al. Androgen glucuronides, instead of testosterone, as the new markers of androgenic activity in women. *J Steroid Biochem Mol Biol.* 2006;99:182-8.

²⁹ Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm529641.htm>. Accessed January 2, 2017.

Locally applied DHEA effectively treats vaginal atrophy symptoms

There is a good deal of research on the benefits and effectiveness (as well as safety) of DHEA in treating vulvar-vaginal symptoms.

The research surrounding vaginally applied DHEA has shown it to:

- Reduce vaginal dryness and irritation
- Strengthen vaginal musculature
- Increase bone mineral density
- Decrease pain during intercourse
- Increase arousal and libido, as well as sexual satisfaction
- **Address vaginal atrophy symptoms without systemic effects**

1. Reduce vaginal dryness and irritation

In a study reported in the *Journal of The North American Menopause Society*³⁰ in 2016, daily intravaginal administration of DHEA caused highly statistically significant improvements in four measurements of vaginal atrophy.

	482 Participants using DHEA (0.50% daily Prasterone for 12 weeks)
Vaginal dryness improvements	1.44 severity score units compared to baseline, or 0.27 units over placebo
Gynecological evaluations	86% to 121% improvements (4 measures) over the placebo
Vaginal pH acidity	Decreased by 0.66 pH units over placebo
Pain during sexual activity	Decreased by 1.42 severity score units from baseline or 0.36 units over placebo

In this study and in earlier studies local Prasterone (DHEA) resulted in these improvements with minimal changes in serum steroid levels.³¹ In one earlier 2009 study, 216 women were given 3 different daily doses of Prasterone, **0.25%, 0.50% and 1.0%**. All three doses results in highly significant beneficial changes in vaginal secretions, a decrease in vaginal pH, epithelial surface thickness, color, and epithelial integrity.

2. Strengthen vaginal musculature

In another 2009 study, DHEA was applied locally within the vagina resulting in a significant improvement to all three layers of the vagina (epithelium, lamina propria and muscularis) versus simply affecting the superficial epithelial cells.³²

The author has numerous case studies demonstrating improvements in vaginal musculature as well as urinary incontinence issues through the use of locally applied DHEA.

³⁰ F. Labrie, D.F. Archer, W. Koltun, et al. Efficacy of intravaginal dehydroepiandrosterone (DHEA) on moderate to severe dyspareunia and vaginal dryness, symptoms of vulvovaginal atrophy, and of the genitourinary syndrome of menopause. *Menopause*. 2016 Mar;23(3):243-256.

³¹ Fernand Labrie, MD, PhD, David Archer, MD, Ce'line Bouchard, MD, et al. Intravaginal dehydroepiandrosterone (Prasterone), a physiological and highly efficient treatment of vaginal atrophy. *Menopause: The Journal of the North American Menopause Society*. 2009;16(5):907-922.

³² F. Labrie, D.F. Archer, C. Bouchard, et al. Effect of intravaginal dehydroepiandrosterone (Prasterone) on libido and sexual dysfunction in postmenopausal women. *Menopause: The Journal of the North American Menopause Society*. 2009 Sept-Oct;16(5):923-31.

3. Increase bone mineral density

In clinical studies, locally applied DHEA has been found to increase bone mineral density³³ and to result in an increase in serum osteocalcin, a marker of bone formation.³⁴

4. Decrease pain during intercourse (dyspareunia)

In a clinical trial in 2015 using intravaginal Prasterone (**6.5 mg** daily for 12 weeks) there was a statistically significant beneficial effect on moderate to severe dyspareunia.³⁵ The authors also noted that vaginal dryness and dyspareunia presented together in **70-80%** of women.

In the same authors' 2016 study the results from the 2015 trial were confirmed. The 2016 trial included **558** postmenopausal women with moderate to severe dyspareunia as their most bothersome vaginal atrophy symptom. Results were once again statistically significant for beneficial effects at the daily intravaginal dose of **0.50% (6.5 mg)** of Prasterone.³⁶

5. Increase arousal and libido, as well as sexual satisfaction

In the 2009 study, 1.0% (13 mg) DHEA applied locally within the vagina resulted in a marked improvement to four aspects of sexual dysfunction: desire, arousal, pleasure and orgasm.³⁷

	1.0% vaginal DHEA over a 12 week period
Improvements in desire	23% versus placebo
Improvements in arousal and lubrication	139% versus placebo
Improvements to orgasm	75% versus placebo
Improvements in dryness during intercourse	57% versus placebo

In a 2015 study the long-term effect on the sexual function of **154** postmenopausal women reporting some form of vaginal atrophy was evaluated based on a 52-week treatment with daily intravaginal **0.50% (6.5 mg)** DHEA. pubococcygeus

Results showed increases as follows: desire, arousal, lubrication, orgasm, satisfaction and pain were improved by **28%, 49%, 115%, 51%, 41% and 108%**, respectively.³⁸

6. Address vaginal atrophy symptoms without systemic effects

A good deal of research supports symptom relief without systemic effects:

³³ F. Labrie, V. Luu-The, C. Labrie, et al. Endocrine and intracrine sources of androgens in women: inhibition of breast cancer and other roles of androgens and their precursor dehydroepiandrosterone. *Endocr Rev.* 2003 Apr;24(2):152-82.

³⁴ F. Labrie, P. Diamond, L. Cusan, J.L. Gomez, A. Be' langer, B. Candas. Effect of 12-month dehydroepiandrosterone replacement therapy on bone, vagina, and endometrium in postmenopausal women. *J Clin Endocrinol Metab.* 1997;82:3498-3505.

³⁵ D.F. Archer, F. Labrie, C. Bouchard, et al. Treatment of pain at sexual activity (dyspareunia) with intravaginal dehydroepiandrosterone (Prasterone). *Menopause: The Journal of The North American Menopause Society.* 2015 Sep;22(9):950-63.

³⁶ F. Labrie, D.F. Archer, W. Koltun, et al. Efficacy of intravaginal dehydroepiandrosterone (DHEA) on moderate to severe dyspareunia and vaginal dryness, symptoms of vulvovaginal atrophy, and of the genitourinary syndrome of menopause. *Menopause: The Journal of The North American Menopause Society.* 2016 Mar;23(3):243-56.

³⁷ F. Labrie, D.F. Archer, C. Bouchard, et al. Effect of intravaginal dehydroepiandrosterone (Prasterone) on libido and sexual dysfunction in postmenopausal women. *Menopause: The Journal of the North American Menopause Society.* 2009 Sept-Oct;16(5):923-31.

³⁸ C. Bouchard, F. Labrie, L. Derogatis, VVA Prasterone Group, et al. Effect of intravaginal dehydroepiandrosterone (DHEA) on the sexual function in postmenopausal women: ERC-230 open-label study. *Horm Mol Biol Clin Investig.* 2016 Mar;25(3):181-90.

- (2015) Study looked at the effects of intravaginal DHEA on the endometrium (tissue lining the uterus) in postmenopausal women. Results showed that the DHEA acted exclusively in the vagina and did not increase serum sex steroid levels.⁵⁸
- (2016) A study focused on dyspareunia. It again confirmed that intravaginally applied DHEA had strictly local action with no adverse effects and that there were highly statistically significant positive effects on four parameters including: vaginal pH, percentage of parabasal cells, percentage of superficial cells, and moderate to severe pain during sexual activity.⁵⁹
- (2016) A study showing symptom relief with estrogenic activity to be below normal postmenopausal values after a low daily dose (6.5mg) of DHEA (Prasterone).⁶⁰
- (2017) Comparison between intravaginal DHEA and estrogens. Results found that the DHEA was as effective for treatment of vaginal atrophy symptoms without systemic effects.⁶¹
- (2018) A study showing that vaginally applied DHEA has no systemic effects outside the postmenopausal range for hormone concentration. This study focused on women with a history of cancer and also evaluated the impacts on bone turnover and vaginal pH. There were more favorable effects compared to vaginal moisturizer relating to symptom relief and vaginal pH (there was no change in bone turnover in either population).⁶²
- (2018) NAMS and the International Society for the Study of Women's Sexual Health published a guideline for women with or at high risk for breast cancer stating that initial treatments should be non-hormonal or low-dose vaginal hormone therapies (after consulting with their oncologist). They cited research finding there was a slight increase in plasma estradiol to the lower half of postmenopausal values after DHEA (Prasterone) administration that was well within normal ranges.⁶³
- (2019) A review focused on Prasterone (DHEA) and its effectiveness and safety profile.⁶⁴

There have been a number of other studies supporting DHEA's effectiveness when applied locally, including several summary papers.

- (2018) The American Society of Clinical Oncology (ASCO), in their 2018 Practice Guidelines for women with cancer and cancer survivors, recommended non-hormonal therapies and low-dose vaginal estrogen as initial treatments. They also recommended that should these women be taking aromatase inhibitors clinicians offer vaginal DHEA.⁶⁵
- (2018) A 12 week study that found that both vaginally applied DHEA and moisturizer provided vaginal atrophy relief, but only the DHEA resulted in significantly improved sexual health. Note that sexual health was measured by use of the Female Sexual Function Index (FSFI). The FSFI is a multi-dimensional measure of 19 categories that addresses the major domains of female sexual functioning, including desire, arousal, lubrication, orgasm, satisfaction, and pain.⁶⁶
- (2018) A good overview of treatment options for postmenopausal vaginal atrophy, includes vaginally applied DHEA.⁶⁷
- (2019) A review focused on using intravaginal DHEA to treat moderate to severe dyspareunia. It discusses the development of the synthetic DHEA drug, Prasterone, which was approved in late 2016 by the US Food and Drug Administration (FDA) for the treatment of this condition.⁶⁸
- (2019) Position statement by the Polish Menopause and Andropause Society relating to the FDA approved vaginally applied DHEA product (Intrarosa®). I'm including it as it is a good overall review of much of the research behind DHEA.⁶⁹
- (2019) Overview of the wide variety of treatment options for various vaginal atrophy symptoms and includes vaginally applied DHEA.⁷⁰

Locally applied DHEA and breast cancer

More than 60% of postmenopausal women having breast cancer report symptoms of vaginal atrophy (most notably, vaginal dryness and pain).⁴⁰ Many of these women cannot take hormone replacement therapy due to cancer concerns and there haven't been a lot of good options for them. But vaginally applied DHEA has shown to be a promising alternative.

Premenopausal women are also affected either as a byproduct of chemotherapy or an increased use of aromatase inhibitors leading to lower estrogen levels and vaginal atrophy side effects.⁴¹

Research supports use of locally applied DHEA as addressing vaginal atrophy symptoms without an increase in intrinsic estrogenic or androgenic activity, finding that the DHEA instead is transformed intracellularly into androgens and estrogens only in the cells in the vulvar and vaginal layers physiologically in need of these sex steroids. (Menopause, 2009)

For women having had breast cancer this is important as it means that DHEA impacts local cells and tissue where it is applied and has not been found to circulate systemically throughout the blood. It has also been found to address vaginal atrophy symptoms.

Additionally DHEA may be useful in the treatment of breast cancer.

In a 2011 study, published in Eur J Pharmacol researchers concluded that “DHEA suppressed the migration of all breast cancer cell lines, independently of the presence of estrogen receptors, and decreased the expression of ECM-1 protein in Hs578T cells. These results suggest that the mechanism of DHEA actions against breast cancer involves the inhibition of cell proliferation and the suppression of migration, indicating that DHEA could be useful in the treatment of breast cancer.”⁴²

In June of 2011, at the request of North Central Cancer Treatment Group (NCCTG), in collaboration with the National Cancer Institute (NCI) and Mayo Clinic, a DHEA bioadhesive vaginal gel was developed by Gateway Pharmacy for use in a FDA-approved, Phase III clinical trial ([NCT01376349](https://clinicaltrials.gov/ct2/show/study/NCT01376349)). The 2014 clinical trial focused on locally applied DHEA as an alternative to estrogen, to evaluate its effectiveness and to assess how DHEA impacts local cells and tissue. The subjects were postmenopausal women with previous breast or gynecologic cancer with moderate vaginal dryness or pain.

The trial consisted of 441 women from 82 institutions, randomized into 3 arms (3.25 mg bioadhesive vaginal moisturizer with DHEA, 6.5 mg bioadhesive moisturizer with DHEA, and control group using moisturizer alone).

The results have not yet been published but findings showed that DHEA improved vaginal health and overall sexual function more than moisturizer alone; additionally, concentrations of hormones all stayed in the lower normal ranges indicating the vaginal DHEA was working through androgenic means locally at the vagina with only minor systemic effects. You can read an article summarizing the findings at <http://www.theoncologynurse.com/ton-issue-archive/2014-issues/september-october-vol-7-no-5/16248-vagina-l-dhea-may-improve-sexual-function-in-women-with-breast-gynecologic-cancer-ton>

In a more recent 2016 paper in Cancer Biology and Therapy researchers studied the inhibitory effect of DHEA on the growth, migration, and invasion of breast cancer cells. The laboratory study found that DHEA was able to inhibit several steps of the carcinogenesis process in breast cancer cells.⁴³

Note there are a few known cautions relating to DHEA:

- If you are taking Tamoxifen: The research on Tamoxifen has shown that oral DHEA (systemic) converting to estrogen can interfere with Tamoxifen use and can decrease its effectiveness when blood serum levels of DHEAs-S are $>$ or $=$ 90 microg/dL.⁴⁴
- If there is concern about the risk for blood clots. While oral estrogen can increase blood clots, trans-dermal estrogen, progesterone and DHEA have not been shown to increase blood clots.
- In earlier research (1999) women with uncontrolled PCOS and abdominal obesity may be associated with the late promotion of breast cancer stimulated by prolonged intake of DHEA. Typically women with PCOS have elevated circulating levels of DHEA and additional oral DHEA would not be warranted. There isn't research relating to topical DHEA's effects.⁴⁵

The author's clinical experience using DHEA to treat vaginal atrophy

As an Emory trained physician Dr. Anna Cabeca started using androgen therapy in her private practice in 1999. She had patients use bioidentical DHEA and Testosterone vaginally or topically to the vulvar area. These patients initially complained of vaginal atrophy symptoms including vaginal dryness, irritation, experiencing pain during intercourse, and urinary leakage. Many had suffered from libido issues.

She routinely achieved positive results with these patients seeing significant improvements to vaginal dryness, with a reduction in irritation and pain during intercourse. There were regular improvements in libido and sexual satisfaction. Some patients also reported decreased incontinence symptoms. Many patients seeing Dr. Cabeca for possible surgery due to pelvic prolapse and stress incontinence issues were able to avoid surgery altogether once she prescribed vaginal DHEA and testosterone to them (given to improve vaginal tissue integrity prior to surgery).

For these patients, a physical examination verified their reported improvements; there were notable tissue improvements in the lining and within the vaginal ruggations (the normal folds and elasticity) as well as contractility (the ability to contract the muscles of the pelvic floor). This meant more strength, more support to the urethra and bladder too.

The need for a non-prescription option

However, Dr. Cabeca wanted to be able to provide a non-prescription based topical solution that provided the least systemic effect. One that would provide women all over the world with a less embarrassing option to address a significant quality of life and overall health issue associated with aging.

Three years of research along with extensive clinical results led Dr. Cabeca to combine DHEA in cream form with other quality natural ingredients having been shown to be beneficial to the skin and its underlying tissues. Those ingredients included Alpine Rose stem cells, emu oil, Vitamin E Tocopherol, coconut oil and

Shea butter. Dr. Cabeca's research concluded that a **small 5-10 mg** daily dosage of DHEA topically applied achieved excellent symptom improvements.

This combination of DHEA along with the other quality natural ingredients was made available in 2016 as Julva®, a restorative topical cream for the vulva, urethra, and vagina. More on ingredients in a moment.

You can learn more about Julva at www.Julva.com. Along with more information as well as testimonials, you will find extensive Frequently Asked Questions (FAQs).

What customers and practitioners are saying about Julva

Customer satisfaction ratings: On Dr. Cabeca's website store (August 2020 - <https://drannacabeca.com/products/julva>) site, Julva has a product rating of 4.8/5.0 (1272 women) with 97% stating they'd recommend Julva to a friend. On Amazon, Julva has a 4.5/5.0 rating (306 respondents) and again, many positive comments.

Hundreds of women have now joined Julva's subscription service which means automatic recurring shipment of the product. Thousands of women all over the globe now use Julva.

Selected client testimonials

[Young at Age 71 | Intimate and In Love](#): Read about 71 y.o. Kathy, who wasn't ready to give up intimacy with her husband. She tried hormones and a variety of treatments to address vaginal dryness and recurring urinary tract infections (which often are a byproduct of menopause as the vagina's pH becomes less acidic and more prone to infections).

28 y.o. Gina: Gina had been using the Merina IUD (a hormonal contraceptive that is inserted via an intrauterine device for lengthy periods of time of up to five years) and experiencing a reduction in her sex drive as well as vaginal dryness. She tried Julva and found it increased her vaginal moisture, her sex drive, her sensation and her orgasms.

[Breast Cancer Survivor and Julva Fan](#): Read about 65 y.o. Nancy, a breast cancer survivor, who suffered from vaginal atrophy (vaginal dryness, pain, a diminished libido and loss of sensation) and was in need of hormone replacement therapy but knew the risks were too great due to her history of estrogen positive breast cancer.

[More Vibrant and Painfree Intimacy – One Woman's Story](#): Read about 64 y.o. Lisa, with her history of fibroids. Lisa went through multiple attempts with various hormone treatments (one containing hormone disruptors as she later found out!). Learn how Julva helped Lisa.

What women's health and pelvic health specialists are saying about Julva

Here are just a few links to some of the many medical professionals who have endorsed Julva.

Magdalena Wszelaki, Founder of Hormones Balance and a Certified Holistic Coach. [Listen to the podcast](#) where Magdalena talks about her community's positive feedback on Julva.

Dr. Jessica Drummond, DCN, CNS, PT, Founder and CEO of the Integrative Women's Health Institute, focused on empowering women related to pelvic health conditions. Read her article on [Solutions for Vulvovaginal Atrophy](#) which includes Julva as her recommendation for women to use for vulvar atrophy, painful sex, diminished libido, or lack of orgasm sensation. Here's a podcast on [all things vaginal atrophy](#), including Julva, as well.

Dr. Brienne Grogan, PT, DPT (Dr. Bri), Doctor of Physical Therapy specializing in women's health physical therapy with an emphasis on the diagnosis and treatment of pelvic floor disorders. Listen to a recent podcast with Dr. Bri on [all things pelvic health](#) and how she is a big proponent of Julva as part of an overall pelvic health regimen.

Other podcasts and articles focused on vaginal atrophy and Julva include those from, [Wellness Mama](#), [Alexandra Jamieson](#), and [Dr. Steven Masley](#).

The need for Julva® Pro

As Julva turns four in 2020 Dr. Cabeca wanted to create another offering in what she is envisioning to be several new DHEA-containing products.

Julva Pro answers two needs heard from customers and practitioners; one for a vegan product, the other for a professional grade product (stronger and even more emollient) that could be distributed by women's health practitioners and medical spas.

A Vegan-Friendly Julva:

While Julva contains emu oil to promote deep tissue absorption it means the product is not suitable for most vegans. Dr. Cabeca found a beautiful replacement using three Certified Organic oils: *Pentaclethra macroloba* (Pracaxi) seed oil, *Helianthus annuus* (Sunflower) oil, and *Simmondsia chinensis* (Jojoba) seed oil. The health benefits of these oils will be talked about under "ingredients" below.

For those who don't require vegan but who may be concerned about emu oil please note that the emu oil used in Julva is natural and pure. It is fully refined with no chemicals used during processing and contains no added allergens (the manufacturer is 100% certified by the American Emu Association).

Both Julva and Julva Pro are gluten-free, paraben-free, additive-free, non-GMO, estrogen-free, and all natural. The added oils are Certified Organic.

A Professional Grade Julva:

Practitioners have asked for a slightly stronger version of the product (they will also benefit from being able to offer a vegan-compliant offering if needed) branded for them for point-of-sale distribution.

Ingredients for Julva Pro:



- Alpine Rose Stem Cells (Rhododendron Ferrugineum Leaf Cell Culture Extract)
- Coconut Oil
- *Pentaclethra macroloba* (Pracaxi) Seed Oil (Certified Organic)
- *Helianthus annuus* (Sunflower) Oil (Certified Organic)
- *Simmondsia chinensis* (Jojoba) Seed Oil (Certified Organic)
- *Butyrospermum parkii* (Shea Butter) Fruit
- Purified Water
- Glycerin
- Undegraded Carrageenan
- Cetearyl Alcohol
- Undecyl Alcohol (anti-microbial)
- Stearyl Alcohol

Active Ingredient

- Dehydroepiandrosterone (DHEA)

Alpine Rose Stem Cells: The Alpine Rose stem cells in Julva are harvested from Swiss alpine plants and contain unique compounds that help the plant survive extremely challenging environments. The plant stem cells have been shown to increase skin cell replenishment, protect against age-related oxidative stress, have antiviral effects and are loaded with polyphenolic antioxidant compounds.³⁹

³⁹ Available at:

https://mibellebiochemistry.com/app/uploads/2015/03/Alpine-Rose-Active_Ecocert_Certified_Alpine_Rose_Active_Combats_Aging_by_Protecting_Skin_Proteins_CosmeticsDesign_02_2011.pdf. Accessed January 2, 2017.

⁴⁰ Kagan, R., Kellogg-Spadt, S. & Parish, S.J. Practical Treatment Considerations in the Management of Genitourinary Syndrome of Menopause. *Drugs Aging* 36, 897–908 (2019).

⁴¹ Chatsiprosos D, Schmidts-Winkler IM, König L, Masur C, Abels C. Topical treatment of vaginal dryness with a non-hormonal cream in women undergoing breast cancer treatment - An open prospective multicenter study. *PLoS One*. 2019;14(1):e0210967. Published 2019 Jan 24.

⁴² López-Marure R, Contreras PG, Dillon JS. Effects of dehydroepiandrosterone on proliferation, migration, and death of breast cancer cells. *Eur J Pharmacol*. 2011;660(2-3):268-274.

⁴³ López-Marure R, Zapata-Gómez E, Rocha-Zavaleta L, et al. Dehydroepiandrosterone inhibits events related with the metastatic process in breast tumor cell lines. *Cancer Biol Ther*. 2016;17(9):915-924.

Research and sustainability information can be found at <https://drannacabeca.com/blogs/vaginal-dryness/alpine-rose-stem-cells>. The Alpine Rose plant-based stem cell extract used in Julva is harvested from sustainably grown cultivations and is Ecocert certified.

Coconut Oil: Coconut oil provides a safe and natural lubricant found to additionally offer antimicrobial activity due to its high Monolaurin acid content.⁴⁶

***Pentaclethra maculoba* (Pracaxi) Seed Oil (Certified Organic):** Pracaxi oil is derived from the seeds of the *Pentaclethra maculoba* tree from Brazil. It is rich in fatty acids which have emollient (helps with absorption and penetration into the skin), lubricant and anti-inflammatory properties. It is used to support superior topical ingredient delivery for many cosmetics and pharmaceutical offerings. It helps restore natural oils of the skin and is used in skincare products intended to soothe dry, damaged skin (even scarred skin).^{47,48}

***Helianthus annuus* (Sunflower) Oil (Certified Organic):** Sunflower oil contains Vitamin E and other compounds providing antioxidant, anti-inflammatory and antimicrobial properties. The absorbent oil is a source of high levels of linoleic acid which helps to maintain the integrity of the skin's natural water permeability barrier (supporting the skin's ability to retain moisture); ideal for dry and irritated skin.⁴⁹⁻⁵¹

***Simmondsia chinensis* (Jojoba) Seed Oil (Certified Organic):** Jojoba oil enhances the absorption of other ingredients contained in Julva. It also promotes even more rejuvenation of the skin. Its high content of wax esters makes it a great addition as supports the skin barrier and is highly stable (it is often used in moisturizers and sunscreens because it is so resistant to degradation).⁵² ***Butyrospermum parkii* (Shea Butter) Fruit:** Shea butter is a fat extracted from the nuts of the Shea tree (formerly called *Butyrospermum parkii*, now called *Vitellaria paradoxa*) used in many personal care products and cosmetics as an emollient. Research has found that due to its rich supply of fatty acids it helps support the skin's natural barrier function. It's been shown to help fight inflammation and has antioxidant and analgesic properties as well.^{53,54} Studies have found it to be a particularly effective moisturizer for sensitive skin.⁵⁵

Undegraded (Food grade) Carrageenan: This is natural seaweed (*Chondrus crispus*) extract added as a cosmetic stabilizer and as a water-binding agent. Undegraded carrageenan is also used in a lot of "creamy" foods such as ice cream, yogurt, infant formula, salad dressing and the like. In foods it keeps the water-soluble ingredients and oil from separating, while providing a creamier, thicker texture. Many cosmetics manufacturers use it as it provides product stability and also helps with hydration of the skin. Along with being in numerous everyday foods undegraded carrageenan can be found in everything from shampoos to toothpastes.

eidelb). 2014;4(2):259-269.

teric. 2019;22(1):65-72.

⁶⁹ Bińkowska M, Paszkowski T, Violetta SP, Wilczak M, Zgliczyński W. Position statement by Experts of the Polish Menopause and Andropause Society, and the Polish Society of Aesthetic and Reconstructive Gynaecology on the medicinal product Intrarosa®. *Prz Menopauzalny*. 2019;18(3):127-132.

⁷⁰ Kagan R, Kellogg-Spadt S, Parish SJ. Practical Treatment Considerations in the Management of Genitourinary Syndrome of Menopause. *Drugs Aging*. 2019;36(10):897-908.

Undegraded (Food Grade) carrageenan is approved by the FDA for use in food and cosmetics.

It is worth noting that a researcher (Joanne K. Tobacman, M.D.) reported on a study performed back in 2001 using “Degraded” (the form that is not used in food or cosmetics) carrageenan. In this study degraded carrageenan was given in drinking water to rats at high levels. The research found a connection between the consumption of degraded carrageenan and the development of tumors and stomach ulcers in the animals. In her conclusions Tobacman also expressed concern that food-grade carrageenan might somehow be affected.

Her reasoning for drawing this conclusion were two-fold, that food-grade carrageenan could possibly be contaminated with degraded carrageenan somehow; and that the animals’ intestinal bacteria could interact with the carrageenan in some way during the digestive process that could result in degrading the carrageenan, potentially causing inflammation in the intestines. There was no evidence of these conditions in her research, and she drew these conclusions from laboratory studies, not from living organisms.

However, in 2008 Tobacman urged the FDA to rule that undegraded, food-grade carrageenan was unsafe. They did not agree with her findings and maintain that carrageenan is safe. Numerous other agencies around the world concur with this FDA ruling.

Other research has subsequently evaluated undegraded, food-grade carrageenan and deemed there to be no evidence of negative effects, even if consuming it. A 2014 review in particular focused on carrageenan’s safety profile as a food additive in humans.⁵⁶ No research has found findings to the contrary although other articles have been published suggesting more research should be undertaken specifically regarding carrageenan as a food additive.⁵⁷ We are not aware of any research underway focused on concerns relating to the food-grade, undegraded carrageenan used in skincare products.

The Environmental Working Group gives the ingredient their “lower level of concern” rating for use in foods, and a low-hazard, safe rating of “1” on its Skin Deep Database for skincare products.
<https://www.ewg.org/foodscores/ingredients/7365-Carrageenan/>
https://www.ewg.org/skindeep/ingredients/701131-CHONDRUS_CRISPUS_CARRAGEENAN/