

JUVIAGEL

VAGINAL MOISTURIZING GEL

New approach for the treatment
of vaginal dryness and
vulvovaginal candidiasis

At a Glance

Unmet need and market (GSM)

Genitourinary syndrome of menopause (GSM) encompasses the genital (dryness, burning, and irritation), sexual (lack of lubrication, discomfort or pain) and urinary (dysuria, and recurrent urinary tract infections) symptoms.

GSM affects about 50% of postmenopausal women and 43% of mothers experienced a lack of vaginal lubrication in postpartum.

Solution

JUVIAGEL is a non-hormonal moisturizing gel intended for the restoration of vaginal wall/mucosa integrity and vaginal health. Numerous clinical studies have tested the effectiveness of its ingredients both in animal, cultured cell and human experiments.

Unmet need and market (VVC)

Vulvovaginal candidiasis (VVC) causes an estimated half billion infections every year. It's estimated that 75% of women will experience VVC in their lifetime.

Study published in Science Translational Medicine showed that zinc gel treatment of women suffering from recurrent vaginal candidiasis prevented reinfections.

Safety

Only vaginal product that complies with all WHO recommendations.

Hormone free.

Over 35K units have been sold with only positive feedback.

IP protection

“VAGINAL TISSUE REJUVENATION COMPOSITIONS AND METHODS” (US Patent No: 9,375,450, 6-28-2016 and EU Patent No: EP 2734159).

“PHARMACEUTICAL COMPOSITION AND METHOD FOR TREATING OR PREVENTING CANDIDIASIS” (US Patent application number: 63456387)



Unmet need and market - GSM


Vaginal dryness

A condition that results from a decrease in the body's estrogen levels. It is characterized by thinning, dehydration and possible inflammation of the vaginal wall. Not only can sexual intercourse be painful, in many cases it causes a dry, itchy feeling even without any physical impact.

 **Causes:** Menopause, breast-feeding, surgical removal of the ovaries, radiotherapy to the pelvic area, chemotherapy or hormone treatment of breast cancer

Scientific findings

Our research group has extensively investigated the role of vaginal zinc supplementation. Zinc plays an important role in the vaginal extracellular matrix (ECM) composition. With vaginal zinc replacement, the vaginal ECM could be regenerated.¹

 Vaginal dryness prevalence ranges from 13% to 31%, although rates are significantly higher for postmenopausal women (50%), as well as in women treated for breast cancer (63%).

 According to a 2018 study 43% of women experienced a lack of vaginal lubrication 6 months after birth.

 This results that the vaginal moisturizers market is expected to grow and reach USD 3 billion by 2028.

1 Peter Takacs, Bence Kozma, Balazs Erdodi, Attila Jakab, Kindra Larson, Robert Poka, Zinc-containing Vaginal Moisturizer Gel Improves Postmenopausal Vulvovaginal Symptoms: A Pilot Study; Journal of Menopausal Medicine. 2019 Apr;25(1):63-68. 4.



Unmet need and market - VVC

🌿 Vulvovaginal candidiasis

VVC is an exceedingly common mucosal infection of the lower female reproductive tract, caused mostly by the polymorphic opportunistic fungus *Candida albicans*. A member of the normal human microbiota, *C. albicans* commonly colonizes the vaginal lumen asymptotically.

🌿 Latest scientific findings

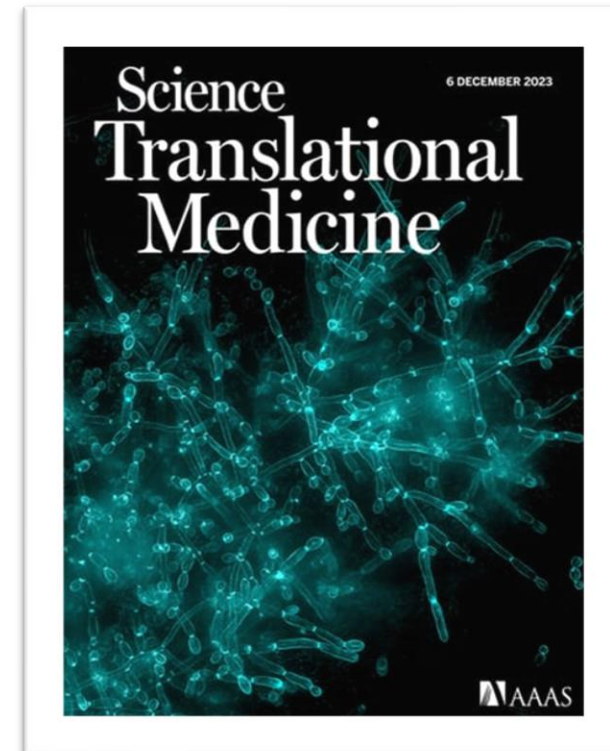
The PRA1 gene is expressed during vaginal infections, and this positively correlates with levels of proinflammatory cytokines in women. Genetic deletion of PRA1 prevented vaginal inflammation in mice and application of a zinc solution down-regulated expression of the gene and blocked immunopathology. Treatment of women suffering from recurrent vaginal candidiasis with a zinc gel prevented reinfections¹.

🌿 Currently, it's estimated that 75% of women will experience vulvovaginal candidiasis (VVC) in their lifetime.


🌿 The fungus *Candida albicans* causes an estimated half billion vaginal candidiasis infections every year.

🌿 The global vulvovaginal candidiasis treatment market size was valued at USD 986.5 million in 2021 and is expected to grow at a compound annual growth rate (CAGR) of 4.39%.

1. E. Roselletti, E. Pericolini, A. Nore, P. Takacs, B. Kozma, A. Sala, F. De Seta, M. Comar, J. Usher, G. D Brown, D. Wilson: Zinc prevents vaginal candidiasis by inhibiting expression of an inflammatory fungal protein
Science Translational Medicine, 6 Dec 2023
Vol 15, Issue 725




Solution

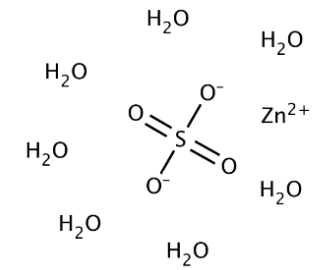
 JUVIAGEL is a natural yet effective vaginal moisturizing gel that takes a new approach to treat vaginal dryness. It is recommended to all women for the treatment of vaginal dryness caused by menopause, pregnancy, infection or other medical conditions. Its unique ingredients have been selected to moisturize the skin and mucous membranes of intimate areas that have special needs.


 Benefits:

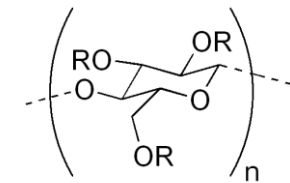
- Hormone free
- It does not leak from the vagina, leaving no mark on the lingerie
- Provides hydration for up to a week
- Can be used as a lubricant during sexual intercourse
- Clear, odorless and homogeneous gel with a pleasant silky touch
- Naturally helps to clean the vagina
- Restores the natural bacterial flora and pH value of the vagina
- Has the same osmolality as natural vaginal fluid
- Complies with WHO regulations
- Glycerin, fragrance and paraben free
- Unique composition protected by international patent
- Only vaginal gel with Zinc


Ingredients

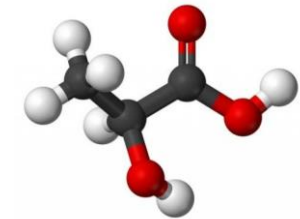
 **Zinc sulphate heptahydrate** has a moisturizing and remodeling effect. It has a direct effect on collagen and elastin composition of the vaginal wall, thus helping to renew the connective tissue elements of the vagina.




 **Hydroxyethyl cellulose** is a universal placebo vaginal gel which is non-toxic, bioadhesive, stable even after long storage and can bind to water molecules for a long-lasting hydration effect.



 **Lactic acid** facilitates the required acidic pH value and supports the natural bacterial flora in the vagina.



 **Sodium chloride** provides isotonicity. The osmolality of NaCl in the gel and natural vaginal fluids are the same. It also protects the mucous membrane from drying.



Scientific background for vaginal Zinc supplementation (animal studies)

- 1. The vagina of female mice held on a zinc deficient diet resembles an atrophic postmenopausal vagina corresponding to menopausal changes. ¹
- 2. The vagina of zinc-deficient mice is similar to that of ovariectomized (OVX) animals ²
- 3. The plasma concentration of zinc in Buffalos with antepartum vaginal prolapse is significantly lower compared to normal pregnant Buffalos during the period 9 months to term ³
- 4. Vaginal zinc supplementation in oophorectomized rats can regenerate the vaginal ECM and create a vaginal ECM typical of juvenile rats. ⁴

1. Taneja S. K., Kaur R.: Pathology of ovary, uterus, vagina and gonadotrophs of female mice fed on Zn-deficient diet; Indian Journal of Experimental Biology, Vol. 28., Nov 1990, pp 1058-1065

2. P. Takacs et al. The Effects of PPARC Agonist and Zinc on Ovariectomized Rats' Vagina. Female Pelvic Med Reconstr Surg 2013;19: 126-131.

3. M.A. Kelkar, S.K. Khar and M. Mandakhot: Studies on antepartum prolapse of the vagina in buffalo- plasma trace element concentration; Arch. exper. Vet. med., Leipzig 43 (1989), 315-318

4. P. Takacs et al. The Effects of PPARC Agonist and Zinc on Ovariectomized Rats' Vagina. Female Pelvic Med Reconstr Surg 2013;19: 126-131.

Scientific background for vaginal Zinc supplementation (human studies)

- 🌿 In humans, tissue zinc levels are lowest during menopause ¹
- 🌿 In human vaginal smooth muscle cell culture, zinc at a tissue level of 20 μM has a beneficial effect on the production of extracellular components produced by muscle, thus increasing collagen and elastatin production and the amount of smooth muscle ²
- 🌿 Novel zinc-containing vaginal moisturizer gel significantly improved postmenopausal vulvovaginal symptoms without serious side effects in women with GSM. ³
- 🌿 The fungus *Candida albicans* causes an estimated half billion vaginal candidiasis infections every year. Study shows that vaginal immunopathology is caused by the *C. albicans* secreted zinc binding molecule Pra1. The PRA1 gene is expressed during vaginal infections, and this positively correlates with levels of proinflammatory cytokines in women. Genetic deletion of PRA1 prevented vaginal inflammation in mice and application of a zinc solution down-regulated expression of the gene and blocked immunopathology. We also show that treatment of women suffering from recurrent vaginal candidiasis with a zinc gel prevented reinfections. We have therefore identified a key mediator of vaginal candidiasis, giving us an unparalleled opportunity to develop a new range of preventative measures for combatting this disease. ⁴

1. Isabelle Bureau, Richard A. Anderson, Josaine Arnaud, Yves Raysiguiet, Alain E. Favier and Anne-Marie Roussel: Trace mineral status in postmenopausal women: impact of hormonal replacement therapy; *J. Trace Elem. Med. Biol.* Vol. 16. p 9-13. (2002)

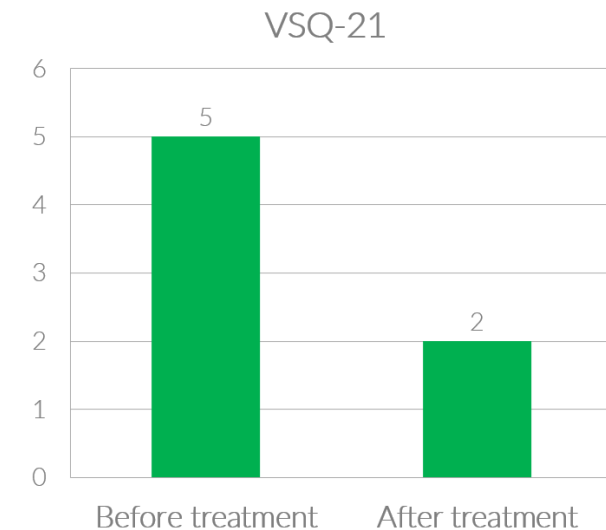
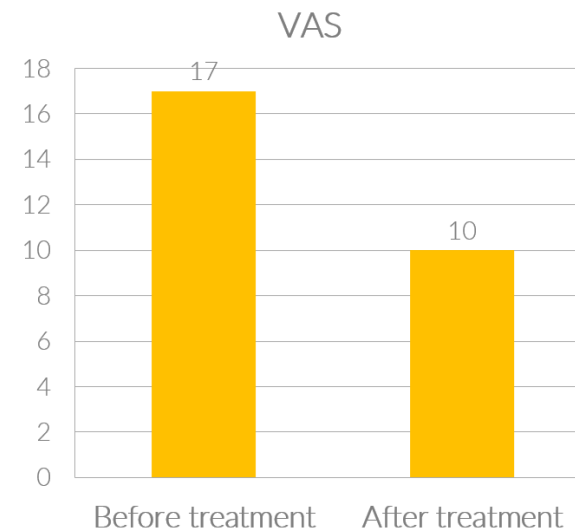
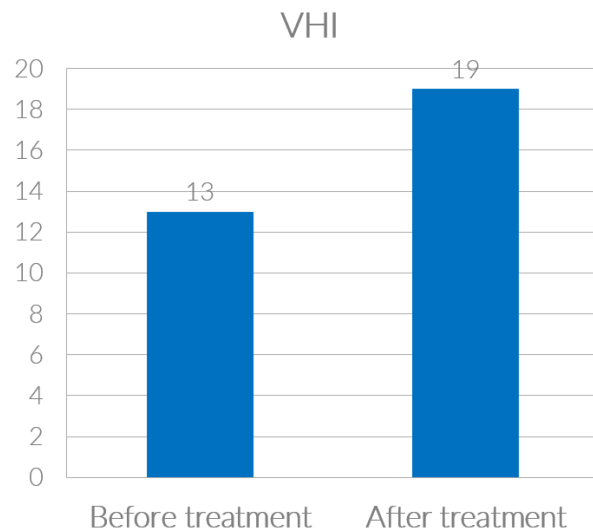
2. P. Takacs et al. Effects of PPAR-delta agonist and zinc on vaginal smooth muscle cells collagen and tropoelastin production. *Int Urogynecol J* (2012) 23:1775-1779.

3. Peter Takacs, Bence Kozma, Balazs Erdodi, Attila Jakab, Kindra Larson, Robert Poka. Zinc-containing Vaginal Moisturizer Gel Improves Postmenopausal Vulvovaginal Symptoms: A Pilot Study. *Journal of Menopausal Medicine* 2019;25:63-68.

4. E. Roselletti, E. Pericolini, A. Nore, P. Takacs, B. Kozma, A. Sala, F. De Seta, M. Comar, J. Usher, G. D Brown, D. Wilson: Zinc prevents vaginal candidiasis by inhibiting expression of an inflammatory fungal protein
Science Translational Medicine

Efficacy of JUVIAGEL - GSM

- ☞ In order to examine the therapeutic effects of JUVIAGEL, an eight-month long clinical study was conducted in 2018 at the Department of Obstetrics and Gynecology at the University of Debrecen in Hungary. ¹
- ☞ The largest incremental VHI component change occurred in vaginal moisture.
- ☞ In sixty percent of the women, the vaginal pH remained normalized (pH < 4.6) even 2 weeks after cessation of treatment.
- ☞ 82% of participants felt more self-confident after using the gel and reported a significant improvement in the quality of the sexual relationship.

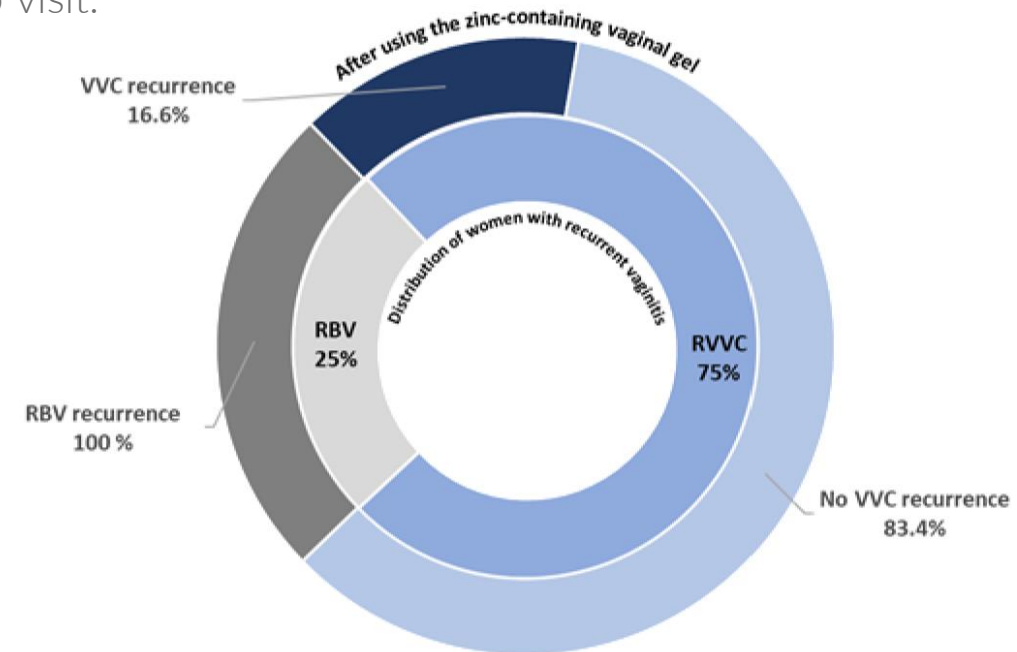


1. Peter Takacs, Bence Kozma, Balazs Erdodi, Attila Jakab, Kindra Larson, Robert Poka, Zinc-containing Vaginal Moisturizer Gel Improves Postmenopausal Vulvovaginal Symptoms: A Pilot Study; Journal of Menopausal Medicine. 2019 Apr;25(1):63-68. 4.

Efficacy of JUVIAGEL - VVC

- ☞ A retrospective cohort study was performed with the enrolment of 10 women with a history of recurrent vaginal infections at the outpatient clinic of the Department of Obstetrics and Gynecology, University of Debrecen, Hungary.
- ☞ Recurrent vaginal infection included recurrent bacterial vaginosis (RBV) and recurrent vulvovaginal candidiasis (RVVC). Enrolment criteria included the presence of RBV or RVVC and recurrent vaginal infection was defined as three or more vaginal infections in the last 12 months (ACOG Practice Bulletin).
- ☞ Women were asked to use JUVIAGEL as prophylactic treatment for two consecutive weeks and, after that, twice per week. They were asked to return to the clinic if any symptoms of vaginal infection were present for evaluation. Patients underwent a detailed gynecological exam at enrolment and the follow-up visit.
- ☞ After being treated with a prophylactic treatment with a commercially available zinc-containing vaginal gel JUVIAGEL, results showed 62% reduction in infection.¹

1. Kozma B, Sipos AG, Pázkózy K, Takács P. Zinc-containing vaginal gel for the prevention of recurrent vaginal infections: a pilot trial. Poster presentation at the 2022 American Urogynecologic Society and International Urogynecological Association's 47th Annual Meeting. June 14-18, 2022. Austin, Texas.



Safety of JUVIAGEL

- ☞ Sold over 35.000 boxes since 2017 with no complaints. There are no side effects reported at recommended doses. No serious adverse events have been reported with usage.
- ☞ JUVIAGEL is manufactured in a GMP complying factory and the whole product lifecycle is managed under ISO 13485.



ISO 13485:2016

Intellectual Property Protection

- 🌿 The scientific foundation for product development for GSM has been granted under the US Patent entitled “VAGINAL TISSUE REJUVENATION COMPOSITIONS AND METHODS (US Patent No: 9,375,450, 6-28-2016 and EU Patent No: EP 2734159).
- 🌿 A patent application was filed for VVC treatment under the US patent entitled “PHARMACEUTICAL COMPOSITION AND METHOD FOR TREATING OR PREVENTING CANDIDIASIS” (Application number: 63456387)
- 🌿 “JUVIAGEL” trademarked by EUIPO.

Availability

- 🌿 JUVIAGEL is on the Hungarian market since 2017. It's on the shelves of Drogerie Markt (DM) and Rossmann as well as can be purchased in pharmacies.
- 🌿 Sold over 35.000 boxes.
- 🌿 Due to the new medical device regulations in the EU, JUVIAGEL is under reclassification to MDR Class IIb. Dossier for registration is available.

Product



JUVIAGEL has been developed for women suffering from vaginal dryness. It nourishes and moisturizes the mucous membrane of the sensitive, dry vagina.

44 ml e gel content
Package Contents:
- 44 ml gel in aluminum tube
- Vaginal applicator packed in foil
- Instruction manual / User's Guide

The gel exerts its effect in the vagina. It is recommended to use daily before bedtime in the first two weeks. Frequency of use is later determined by individual comfort (usually 1-3 times a week). The attached vaginal applicator can be drained to the end of the tube to draw the desired amount of gel (approximately 2 ml). The gel can be applied to the vagina using the applicator.

The gel can act as a lubricant during sexual activity.

Contact us

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