

A non-hormonal and non-steroidal gel for

- Vaginal atrophy
- Lichenoid dermatoses (sclerosus / planus)



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Ideal for short- and long-term use

# Vaginal atrophy and Lichenoid dermatoses

Quality of life of many women can be significantly impacted by **vulvovaginal symptoms** such as vaginal dryness, burning sensation, itching and tenderness as well as painful intercourse (dyspareunia), painful urination (dysuria) and bowel movement (defecation). These symptoms can cause **significant distress** on physical, mental, and sexual health, **for women** at different stages of their life.

Vaginal atrophy (VA; Also known as Genitourinary Syndrome of Menopause, GSM), vulval Lichen sclerosis (LS) and vulvovaginal Lichen planus (LP) are the most common disorders associated with these symptoms.<sup>1-5</sup>

Approximately **70% of women** with the above symptoms **do not discuss the issue** with their Health Care Providers and 40% expect doctors to initiate this conversation.<sup>6,7</sup>

## Vaginal atrophy and current treatment options

VA is a common genital condition affecting:

- **40%-57% of postmenopausal women**<sup>8</sup> with some reports showing a prevalence **up to 90%**.<sup>9</sup>
- Up to **70% of patients affected by breast cancer** present menopausal symptoms.<sup>8</sup>
- **15% of the female population** experiences symptoms of VA **before menopause**.<sup>7</sup>

Vaginal dryness is the most prevalent and bothersome symptom as it affects up to 93% of women with VA.<sup>10</sup>



**Lubricants and moisturizers** provide temporary relief from vaginal dryness and pain during intercourse, and are suitable mostly for women with mild symptoms.<sup>10</sup>

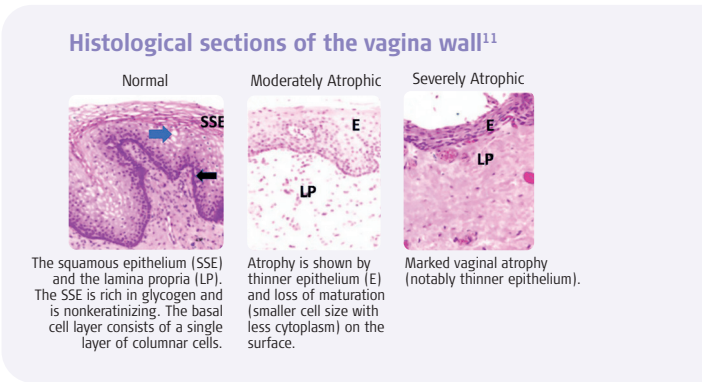
**Hormonal therapy** is a common treatment of VA, and includes estrogen-based treatments that can be administered vaginally, orally, trans-dermally or subcutaneously. Vaginally administered products show better results than the others.<sup>10</sup> **Excess estrogen** levels are associated with **side effects** such as an increased risk of heart disease, breast cancer, thromboembolic complications, and cerebrovascular diseases.<sup>12</sup>

**Phytoestrogens** could provide temporary relief of symptoms, however, due to **insufficient clinical data and limited efficacy**, they cannot be recommended as an alternative treatment option.<sup>10,12</sup>

The American College of Obstetricians and Gynecologists (**ACOG**) and the American Society of Clinical Oncology (**ASCO**), recommend the use of **non-hormonal options as the first choice for treatment of VA** in women with current or a history of estrogen-dependent breast cancer.<sup>8,13</sup>

Minimally invasive procedures, using **laser and radiofrequency devices**, have been introduced to reduce VA symptoms and are often referred to as **vaginal rejuvenation**. The most common **side effects** of vaginal rejuvenation are burning sensation, discomfort, swelling and redness.<sup>14</sup>

Achieving **symptomatic relief and finding an effective treatment for long-term use without side effects** is **crucial** for both physicians and patients.<sup>8,10</sup>



## Lichenoid dermatoses and current treatment options

Lichenoid vulvar dermatoses, which include lichen sclerosis (LS), lichen planus (LP) and lichen simplex chronicus (LSC), are chronic, progressive, inflammatory conditions that are characterized by epithelial thinning and can manifest with a variety of symptoms, most commonly pruritus or pain.<sup>15</sup>

LS and LP are most prevalent in females **during prepubertal and postmenopausal period**. Affected women are at lifetime risk of developing squamous cell carcinoma (SCC), and **up to 65% of vulvar carcinomas** originate from LS.<sup>1,16</sup>

Patients with LSC report **intense pruritus** that may disturb sleep. Heat, sweat, and friction may worsen the pruritus and symptoms can remain despite the removal of triggers. Clinical manifestations include **lichenified plaques** and an unilateral or bilateral increase in skin folds.<sup>17</sup>

**Potent and very potent topical corticosteroids** are commonly used for Lichenoid dermatoses treatment.<sup>1,18</sup> Side effects associated with **long-term use of topical corticosteroid** are telangiectasia (skin transparency), skin atrophy, Striae (stretch marks) formation, rebound reactions, reactivation of human papilloma virus (HPV) and herpes simplex virus (HSV) infection.<sup>19,20</sup> The use of topical corticosteroids **should be discontinued** if no improvement is seen after regular follow-up and treatment for 6 months.<sup>1</sup>

**Laser therapy** reduces symptoms but **does not prevent recurrences**.

**Retinoids** decrease connective tissue degeneration. However, the use of these agents is limited due to their **side effects** such as cheilitis, xerosis, teratogenicity, elevated liver enzymes, elevated triglycerides, and alopecia.<sup>1</sup>

While vulvovaginal diseases are chronic in nature, **symptomatic control and improvement of Quality-of-Life** is possible for most women.<sup>8,10</sup>



## StrataMGT® - the innovative gel for the management of mucosal conditions

StrataMGT is a **non-hormonal and non-steroidal gel**.

StrataMGT **supports** vulvovaginal mucosal conditions and **speeds up** recovery post vaginal rejuvenation.

StrataMGT is a **suitable alternative** to vaginally administered estrogen and topical corticosteroids.<sup>21</sup>

StrataMGT **promotes** a moist healing environment leading to **faster re-epithelialization**.

StrataMGT **relieves symptoms** such as itchiness, tenderness, dryness, burning sensation, painful intercourse (dyspareunia), painful urination (dysuria), rectal and defecating pain.<sup>22</sup>

StrataMGT **improves** erythema, mucosal tissue thinning, erosions, fissures, ulcerations, scarring/adhesions and swelling.<sup>21</sup>

StrataMGT is indicated **for long-term use** to maintain the health of the vulvovaginal mucosa **without the side effects** of vaginally administered hormonal therapy and topical corticosteroids.

StrataMGT is FDA Registered Class I Medical Device.



# Clinical evidence for StrataMGT®

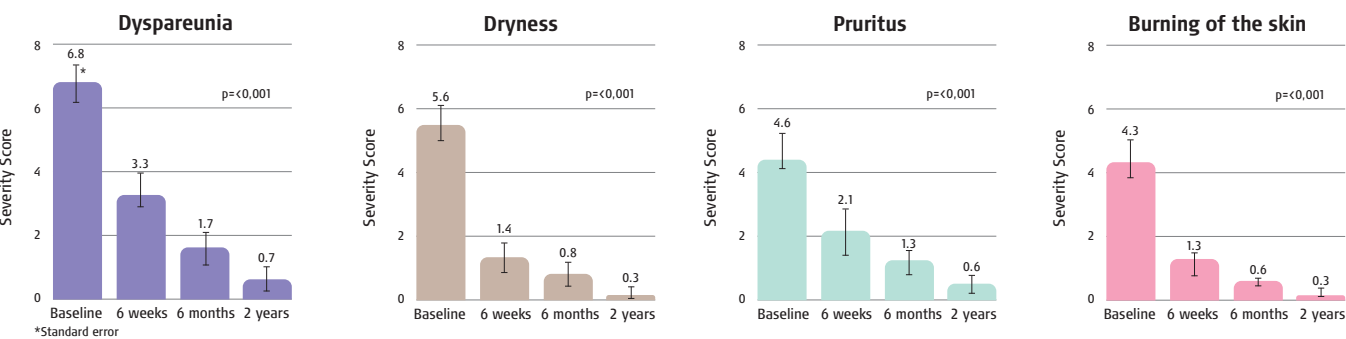
A 52-women open-label, single-arm intervention study was conducted in St. Andrews War Memorial Hospital in Brisbane, Australia to evaluate the efficacy and safety of StrataMGT for the management of genital skin conditions.<sup>21</sup>

Patients were diagnosed with Vaginal atrophy (VA), mean age of 66.3 (range 50 - 74 years); Lichen Sclerosus (LS) and Lichen Simplex Chronicus (LSC), mean age of 54.7 (range 19 - 81 years).

Patients applied StrataMGT daily internally and externally to the genital area for approximately 6 months (short-term analysis, n=52) and up to 2 years (long-term analysis, n=30).

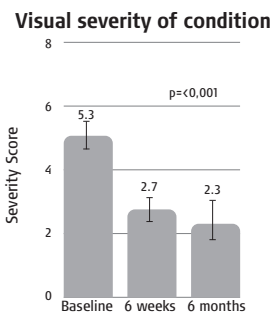
- **Severity of the symptoms:** Patients rated severity of the symptoms using a 10-point scale ranging from 0=normal to 10=worst possible.

The most significant **improvements were seen during the first 6 weeks**, where **symptoms improved up to a 100% resolution** for some patients. **Favorable results** were maintained over **2 years post start of the treatment**.



- **Severity of the condition:** The investigator rated the visual severity of the condition using a 10-point scale ranging from 0=normal to 10=worst possible.

The visual **severity of pathology and clinical signs improved significantly compared to baseline**. The visual pathology of the clitoral hood, urethral area, labia majora and minora, fourchette and perineum showed statistical improvement.



StrataMGT reduces Trans-Epidermal Water Loss (TEWL) by preventing water loss from epidermal and dermal layers, and gas permeability enables **better environment for epidermal migration and healing**.

Treatment **compliance** was very high throughout the study, between 86% and 97% in each visit interval. **No adverse events** were observed.

- StrataMGT is a **suitable alternative** treatment for women suffering from various highly symptomatic vulvovaginal conditions.
- StrataMGT is recommended as a **long-term treatment option without the side effects** of topical corticosteroids and vaginally administered hormonal therapy.

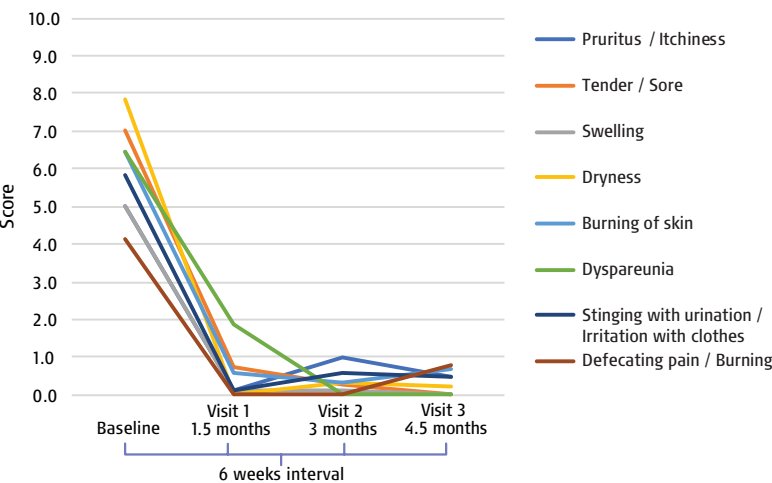
# Clinical evidence for StrataMGT®

Case series with 19 patients to test the efficacy of StrataMGT on patients presenting for treatment of chronic uncontrolled vulvovaginal conditions, such as Vaginal atrophy (VA) and Lichen Sclerosus (LS).<sup>22</sup>

Dr. Philip Hall, Gynaecologist, MBBS MRMed, FRANZCOG, FRCOG, FACRRM. Pelvic Medicine Centre, St Andrew's War Memorial Hospital Spring Hill Brisbane Australia (2018).



**Severity of the symptoms:** Patients rated severity of the symptoms using a 10-point scale ranging from 0=normal to 10=worst possible.



Patients were followed up over 3 visits (V1-3), averaging 6 week intervals.  
Patients mean age of 53.5 (range 30 - 77 years).

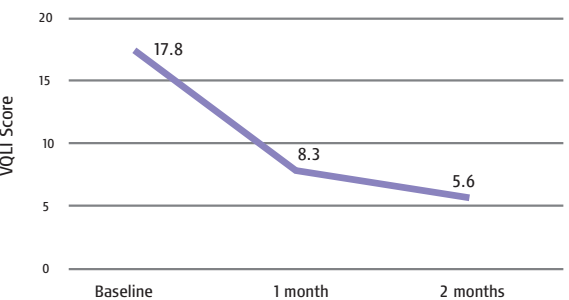
StrataMGT provides **hydration whilst protecting the epithelium and mucosa from irritants** such as urine, infection and friction.

The **most significant improvement** was seen for all patients within the first 6 weeks, where **symptoms improved from 33% through to 100% resolution** in some patients.

The clinical control of symptoms was maintained over Visit 2 (3 months) and Visit 3 (4.5 months) in the majority of patients.

A 9-women non-uncontrolled, open-label intervention study was conducted in Orange Coast Women's Medical Group in Laguna Hills, California, USA to evaluate the efficacy and safety of StrataMGT and the improvement of patient's Quality-of-Life (QoL). All patients were postmenopausal, diagnosed with VA, and treated with StrataMGT for 2 months.<sup>23</sup>

Patients rated the impact of vulvar conditions on QoL using Vulvar Quality of Life Index (VQLI) ranging from 0=not impacted, 1-15=mildly impacted, 16-30=moderately impacted, 31-45=severely impacted.



- **The most significant improvement** was seen during the **first month** of treatment - the VQLI score **was reduced by 54%**.
- StrataMGT is **highly efficient** in reducing clinical symptoms associated with VA and improving QoL.

# StrataMGT® indications

StrataMGT is used to restore the barrier function and moisture balance of the mucosal epidermis.

StrataMGT was developed for use on all types of mucosal conditions and post-procedures care, including:

- Vaginal atrophy
  - Atrophic vaginitis
  - Genitourinary syndrome of menopause (GSM)
  - Vulvovaginitis (including pre-pubertal)
  - Vulvodynia
- Lichen sclerosus/planus
  - Lichen simplex chronicus
  - Post vaginal rejuvenation
  - Vaginal grazing
  - Episiotomy
- Incontinence related dermatitis
  - Diaper rash
  - Hemorrhoids and anal fissures
  - Allergic and irritant dermatitis

# Why is StrataMGT® an innovative product?

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**MUCOSAL HEALING**  
StrataMGT may be directly applied to dry, wet, cracked and sensitive mucosal tissue.
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**FASTER HEALING**  
StrataMGT promotes a moist healing environment leading to faster re-epithelialization, and reduces the acute inflammatory response.
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**SYMPTOMATIC RELIEF**  
StrataMGT relieves symptoms such as itchiness, tenderness, dryness, burning sensation, painful intercourse (dyspareunia), painful urination (dysuria) and rectal or defecating pain.
- 

**RESTORES BARRIER FUNCTION**  
StrataMGT temporarily restores the barrier function of the mucosa.
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**HYDRATION AND GAS PERMEABILITY**  
StrataMGT is semi-permeable, which allows the mucosa to breathe and remain hydrated.
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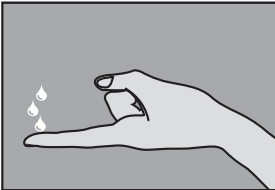
**NON-REACTIVE**  
StrataMGT is inert, has no measurable pH, contains no hormones, steroids, alcohol, parabens or fragrances, and is suitable for long-term use.
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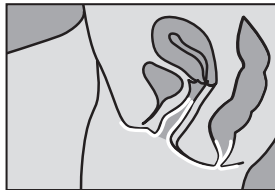
**NON-ABSORBABLE**  
When used inside the vagina or rectum, StrataMGT will not be absorbed systemically.



# Directions for use

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1. Wash your hands before applying StrataMGT.
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2. When used vaginally, apply 3 to 5 drops of StrataMGT on the tip of your finger.\*
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3. Distribute StrataMGT evenly internally and externally as required.

\*Some patients prefer to use a common vaginal applicator for intravaginal application.

# How much StrataMGT® do I need?



- StrataMGT gel is an advanced formulation that requires **substantially less gel per application** than typical creams or gels
- StrataMGT 1 oz (28.4 g) contains enough gel for approximately 4 weeks of use 2-3 times per day.
- Patients with different symptoms or diagnoses may require more-or-less product or numbers of applications per day.
- Generally, patients will understand how much and how often to apply for their relief within a few days.

# Duration of treatment

StrataMGT should be applied for a minimum of 30 days.

StrataMGT is indicated for long-term use to maintain the health of the mucosa, and should be continued as required.

# Additional directions

- For best results StrataMGT should be maintained in **continuous contact** with the affected area (24 hours a day / 7 days a week).
- StrataMGT should be applied as **needed** or as advised by the physician.
- StrataMGT may be re-applied **more often** to ensure constant contact with the mucosa or skin, or to reduce symptoms.
- StrataMGT should be applied **after each urination, bowel movement or wash**.
- StrataMGT **does not need to be rubbed in or massaged**, as it does not penetrate through the mucosa or skin and will not enhance its effect.
- It is recommended to use panty liners during the first weeks of StrataMGT use, in case of product leaking.
- StrataMGT **may stain** clothing or sheets. If staining occurs, dry cleaning should be able to remove it without damaging the fabric.
- StrataMGT **should not be applied over topical medications** unless advised by your physician.

# StrataMGT® and other products

**Moisturizers, lotions, etc. are not required.** StrataMGT can be re-applied more often to avoid dry and tight skin feeling, as StrataMGT prevents the water evaporation through the damaged mucosa that may cause this feeling.

StrataMGT **may reduce the effectiveness of contraception** such as spermicides, condoms or vaginal devices. Please use other precautions during this time.

StrataMGT **may increase lubrication** and therefore should not be used in conjunction with condoms for the prevention of sexually transmitted diseases (STDs).



## StrataMGT® - a non-hormonal and non-steroidal gel for vaginal atrophy and lichenoid dermatoses

- StrataMGT relieves symptoms such as itchiness, tenderness, dryness, burning sensation, painful intercourse (dyspareunia), painful urination (dysuria), rectal or defecating pain.
- StrataMGT improves erythema, mucosal tissue thinning, erosions, fissures, ulcerations, scarring/adhesions and swelling.
- StrataMGT is inert, has no measurable pH, contains no hormones, steroids, alcohol, parabens or fragrances, and is suitable for long-term use.
- StrataMGT is gas-permeable, allowing the vaginal mucosa to breathe and remain hydrated.
- StrataMGT promotes faster healing and is easy to apply at home.
- StrataMGT is ideal for short- and long-term use.



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**Caution:** StrataMGT should not be placed in contact with the eyes. StrataMGT may also be used in conjunction with other treatments when advised by your physician. StrataMGT may reduce the effectiveness of contraception such as spermicides, condoms or vaginal devices. Please use other precautions during this time. StrataMGT may increase lubrication and therefore should not be used in conjunction with condoms for the prevention of sexually transmitted diseases (STDs). StrataMGT may stain clothing or sheets. If staining occurs, dry cleaning should be able to remove it without damaging the fabric. For correct storage please reclose the tube tightly with the cap. For chronic conditions regular surveillance with your physician is recommended. Should you show signs of infection or failure to heal, consult your physician. If irritation occurs, discontinue use and consult your physician. Keep out of the reach of children. Do not use after the expiration (EXP) date printed on the tube. The expiration (EXP) date does not change once the tube has been opened. Do not use if the tube is damaged. StrataMGT does not require special disposal methods. Please follow your local disposal regulations.

**Ingredients:** Polydimethylsiloxanes, siloxanes, alkylmethyl silicones

**References:** 1. Arinkan, S. (2018). *Haydarpasa Numune Med J.*, 58(2), pp.112-115. 2. Aung, T. et al. (2021). *Australian J of General Practice*, 50, pp. 55-59. 3. Nappi, RE. et al. (2019). *Frontiers in Endocrinology*, 10, pp. 561. 4. Ringel, NE, Iglesia, C. (2020). *American family physician*, 102(9), pp. 550-557. 5. Portman, DJ., Gass ML. (2014). *Menopause*, 21(10), pp. 1063-1068. 6. Wysocki, S. et al. (2014). *Clinical medicine insights. Reproductive health*, 8, pp. 23-30. 7. Bleibel, B., Nguyen, H. (2022). Vaginal Atrophy. In StatPearls. StatPearls Publishing. 8. Benini, V. et al. (2022). *Medicina*, 58(6), pp. 770. 9. Palacios, S. et al. (2018). *Climacteric: the J of the International Menopause Society*, 21(3), pp. 286-291. 10. Angelou, K. et al. (2020). *Cureus*, 12(4), e7586. 11. Tadir, Y. et al. (2017). *Lasers in surgery and medicine*, 49(2), pp. 137-159. 12. Ruan, X., Mueck, A. (2018). *Clinical Research and Trials*, 4(6), pp.1-9. 13. Kagan, R. et al. (2019). *Drugs & Aging*, 36, pp.897-908. 14. Arroyo, C. (2017). *International J of Women's Health*, 9, pp. 591-595. 15. Fruchter, R., et al. (2017). *International J of women's dermatology*, 3(1), pp. 58-64. 16. Corazza, M. et al. (2021). *Biomedicine*, 9(8), pp. 950. 17. Barchino-Ortiz, L. et al. (2012). *Actas dermo-sifilograficas*, 103(4), pp. 260-275. 18. Chuh, A. et al. (2006). *Australian Family Physician*, 35(9), pp. 723-725. 19. Chi, CC. et al. (2011). *Cochrane Database of Systematic Reviews*, 2011(12), CD008240. 20. Fistarol, SK., Itin, PH. (2013). *American J of clinical dermatology*, 14(1), pp. 27-47. 21. Data on file, 2022. (St. Andrews War Memorial Hospital, Australia). Stratpharma AG. 22. Hall, P. (2018). *22nd Annual Australasian Menopause Society Congress*. 23. Data on file, 2022. (Orange Coast Womens Medical Group, USA). Stratpharma AG.