

Rx Only
For topical use only
73661-423-50

ADVANCED FORMULATION
Strata mark[®]
for the management
of stretch marks

A breakthrough in the management of stretch marks



Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner.

 **Stratapharma**
Switzerland

Striae Distensae are a form of pathological scarring

Striae Distensae, or stretch marks, are a well recognized and common skin condition that affect **60-70% of pregnant women**¹ and **83% of teenagers**² that can be a cause of **great concern and insecurity**.

Striae are a pathological condition of the connective tissue. The pathogenesises are changes in the extracellular matrix, especially in collagen, elastin and fibrillin.³⁻⁷

Histologically, Striae are **atrophic scars**. The collagen ruptures and the gap is filled with newly synthesized collagen, which aligns in accordance with the local stress forces.⁸

Although they are not detrimental to health, stretch marks can cause **physical symptoms** such as itchiness, tenderness and pain. Because of their visual appearance, they can also significantly affect one's **self-esteem and image**.¹

The development of Striae has been **likened to wound healing or scar formation**.⁹

Studies found **no correlation** between⁵:

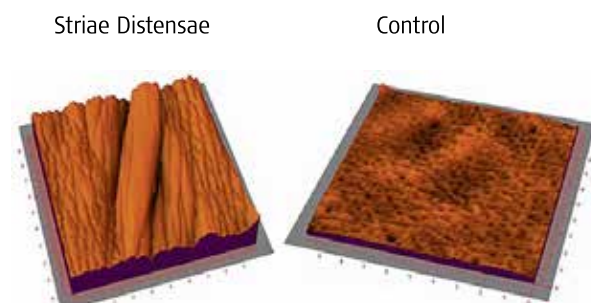
- Striae Gravidarum and weight gain per week.
- Greater percentage increase of abdominal/hip girth during pregnancy and a greater number of Striae.

The strength of the skin's strain is not the primary cause of Striae.⁵

Hormonal changes are one of the main risk factors for the development of stretch marks.^{1,10}

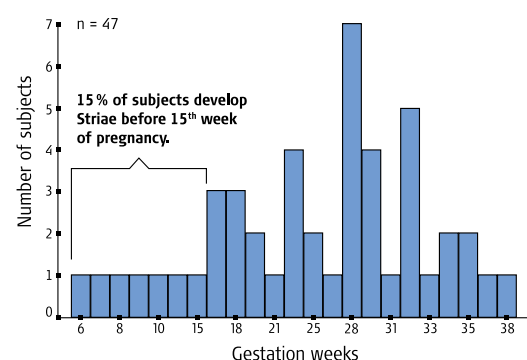
There is **no statistically significant** average difference in the development of stretch marks in women who received topical preparations with active ingredients compared to women who received a placebo or no treatment.¹⁰

Those products that have shown to be successful in treating Striae, for example tretinoin or invasive procedures (i.e. lasers, microneedling, RF etc.) are **contraindicated in pregnancy**.¹¹⁻¹⁴



Three-dimensional representation of skin replicas.¹⁵

Distribution of gestational ages when Striae first appear⁵



Histological comparison of normal skin, Striae Rubrae and Striae Albae¹⁶



Normal skin: randomly arranged small collagen and thin elastin fibers in the papillary dermis, coarse elastic fibers and thick bundles of collagen parallel to the direction on the skin in the reticular dermis.

Striae Rubrae: fine elastic fibers predominate in the dermis with thicker fibers in the periphery; there is a reduction and reorganization of elastin and fibrillin fibers and structural changes in collagen are seen.

Striae Albae: histology demonstrates epidermal atrophy and loss of the rete ridges; densely packed, thin eosinophilic collagen bundles are arranged horizontally, parallel to the surface of the skin in a **similar way to a scar**.

StrataMark indications

StrataMark is intended to be used under the direction of healthcare practitioners in the management of stretch marks.

StrataMark is indicated for the management of all types of stretch marks, particularly those covering a wide surface area, resulting from pregnancy, adolescent growth spurts, weight gain or loss, or bodybuilding.

StrataMark is indicated to soften and flatten stretch marks, reduce redness and discoloration associated with stretch marks as well as to relieve the itching and discomfort of stretch marks.



FILM-FORMING, FLEXIBLE, FULL CONTACT

StrataMark dries to form a thin, transparent and durable protective film that ensures constant contact with the skin (24 hours a day/7 days a week).



SOFTENS AND FLATTENS

StrataMark softens and flattens raised and depressed stretch marks.



SYMPTOMATIC RELIEF

StrataMark relieves the itching and discomfort of stretch marks.



REDUCES REDNESS AND DISCOLORATION

StrataMark reduces redness and discoloration associated with stretch marks.



DIFFERENT AREAS

StrataMark is suitable for all areas of the skin, including exposed and sensitive areas, as well as large areas of the body (i.e. buttocks, abdomen, thighs, breasts and back).



NON-REACTIVE

StrataMark is inert, has no measurable pH, and contains no alcohol, parabens or fragrances and does not penetrate below the level of stratum corneum, making it suitable for pregnant women, breastfeeding mothers, children and people with sensitive skin.



UNIQUE FORMULATION

StrataMark requires substantially less product per application than typical creams or gels.

Mode of action



Hydration: StrataMark is semi-permeable, which allows the skin to breathe and remain hydrated. It is also hydrophobic, which prevents water being lost from the dermal layers of the skin. It helps in decreasing the Trans-Epidermal Water Loss (TEWL) and therefore increasing stretch marks hydration.^{8,17}



Protection: StrataMark forms a durable, flexible and waterproof sheet. It does not penetrate into the epidermis or dermis. StrataMark protects the stretch mark from local irritants including friction from clothing. This assists in normalizing the level of collagen production.⁸



Modulation: StrataMark influences on the epidermal-dermal signaling cascade via a regulation role of the epidermis on fibroblast production. Keratinocytes have shown to activate the fibroblasts, hence collagen and glycosaminoglycan production. This leads to the normalizing of the keratinocyte hydration status and the normalizing of tissue growth factors, which signals dermal fibroblasts to normalize the collagen synthesis cycle of Striae.⁸

StrataMark is clinical proven to prevent and treat stretch marks

A study in Europe was conducted to evaluate the clinical efficacy of StrataMark for the prevention and treatment of Striae Distensae. A total of 303 patients were split into 2 arms and evaluated by 61 obstetricians.¹⁸

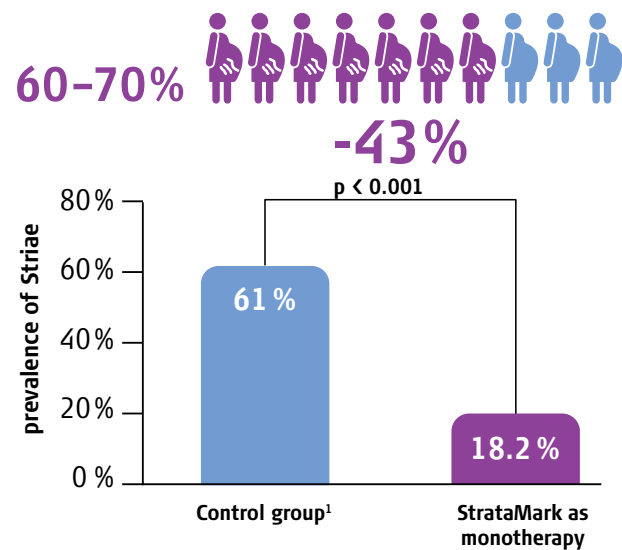
Malkova, S. (2014). 'The Effect of Innovative Gel in the Prevention and Treatment of Striae (StrataMark Gel)', *New EU Magazine of Medicine*, 1-4/4, pp. 1-7.

Prevention arm
n=148 pregnant women with **no** existing Striae at the abdomen area

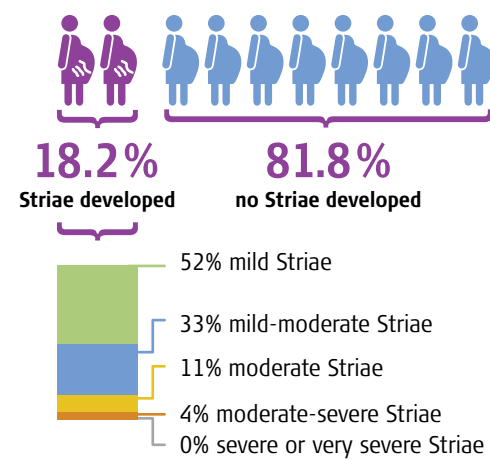
Treatment arm
n=155 pregnant women with **existing** Striae at the abdomen area

Results – prevention arm

Control group



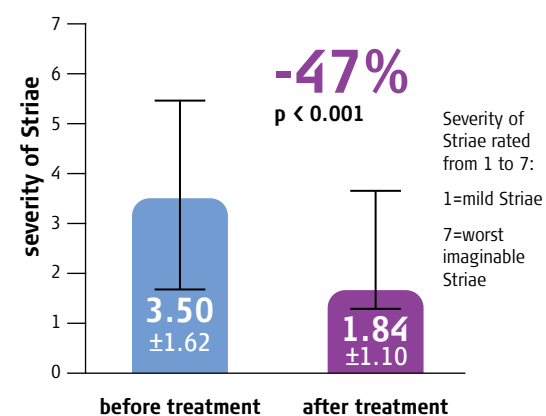
StrataMark as monotherapy group



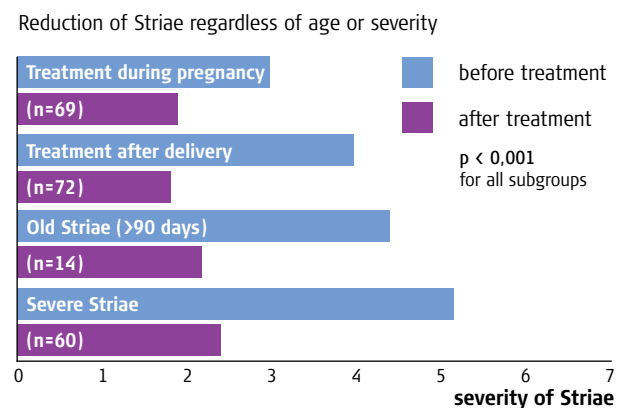
The reported prevalence of Striae ranges between 50-90%, with most control groups showing between 60% and 70% developed during pregnancy, depending on the population studied.¹

Results – treatment arm

Significant reduction in severity of Striae



Subgroup analysis



- 88% reported improvement in color
- 86% reported reduction in visibility
- 83% reported reduction in pruritus

StrataMark is a standalone topical treatment of stretch marks

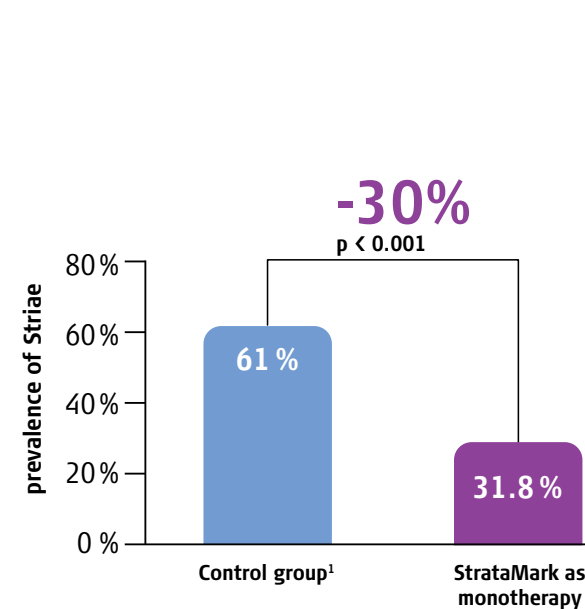
In a multicenter study in Australia, a total of 272 patients were analyzed in the use of StrataMark in preventing and treating stretch marks¹⁹.

Hughes, CD, Hedges, A. (2018). 'The use of an innovative film-forming gel in preventing Striae Gravidarum and treating Striae Distensae', *Australasian Journal of Dermatology*, doi: 10.1111/ajd.12893.

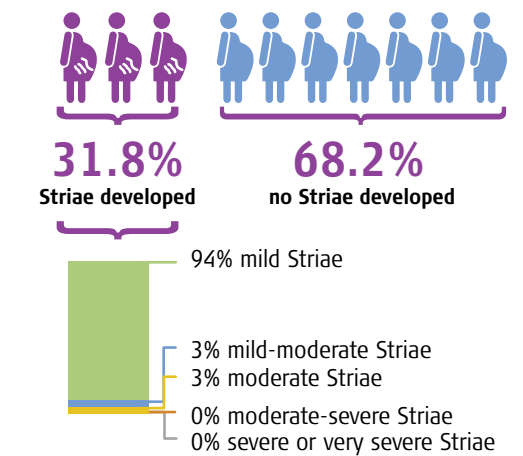
Prevention arm
n=139 pregnant women **without** stretch marks recruited from 26 weeks of gestation

Treatment arm
n=133 post-partum women **with** stretch marks from any cause

Results – prevention arm



StrataMark as monotherapy group



Results – treatment arm



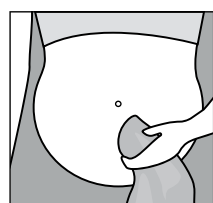
- 73% patients reported improvement in color
- 90% doctors rated StrataMark efficacy as Excellent or Very good



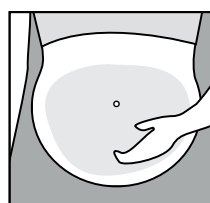
"Considering other effective topical products and invasive procedure are contraindicated during pregnancy, StrataMark currently sits as a standalone topical treatment that is efficacious and safe".

Christopher David Gildas Hughes, Obstetrician and Gynecologist, Adelaide, SA, Australia

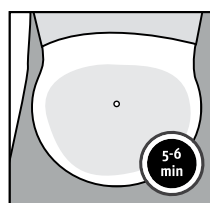
Directions for use



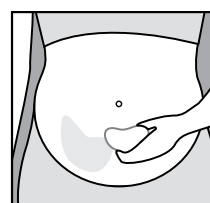
1. Ensure that the skin is clean and dry.



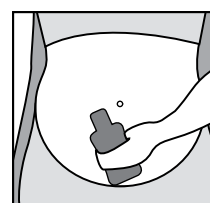
2. Apply a **very thin layer** of StrataMark to the relevant areas with the fingertips and distribute evenly to form a very thin layer and allow the gel to dry.



3. When applied correctly, StrataMark should be **dry in 5-6 minutes**.



4. If it takes longer to dry you have probably applied too much. Gently remove the excess with a clean tissue or gauze and allow the drying process to continue.



5. Once dry, StrataMark can be covered with undergarments, sunscreens or cosmetics.

Additional directions

- StrataMark should be applied **once per day** or as required to maintain contact with the affected surface.
 - StrataMark may be re-applied **more often** to ensure constant contact with the skin, or to reduce symptoms.
 - Washing will likely remove StrataMark. Re-apply StrataMark **after each wash**.
- For best results StrataMark should be maintained in continuous contact with the skin (24 hours a day/7 days a week).
- **StrataMark does not need to be rubbed in or massaged**, as it does not penetrate below the level of stratum corneum and will not enhance its effect.
- If not completely dry, StrataMark may stain clothing. Normal washing will not remove the product from the clothes. If staining occurs, dry cleaning should be able to remove it without any damaging of the fabric.
- StrataMark **should not be applied over topical medications** unless advised by the physician.

StrataMark and other products

Moisturizers, lotions etc. are not required.

StrataMark can be re-applied more often to avoid dry and tight skin feeling, as StrataMark prevents the water evaporation through the damaged skin that may cause this feeling. Alternatively, a moisturizer can be applied after StrataMark dries to maintain the first contact of StrataMark with the skin.

StrataMark **should not be applied over topical medications** unless advised by the physician.

StrataMark may also be used in combination with other invasive stretch mark treatments including laser therapy (non-ablative lasers, microneedling PDL, IPL, Radio Frequency devices) after the re-epithelialization.

IMPORTANT

Due to StrataMark's semi-permeable nature:

- StrataMark may enhance the effect of an active ingredient if StrataMark is applied over the active ingredient.
- StrataMark may prevent or reduce absorption of active ingredients if they are applied over StrataMark.

Duration of treatment

During pregnancy: StrataMark is recommended for use from the beginning of the second trimester (13 weeks) or at the first sign of stretch marks. Treatment should be continued following birth for a minimum of 60 to 90 days.

During growth spurts: StrataMark should be used for the duration of the growth spurt or until the skin is no longer tightly stretched. Treatment should then be continued for 60 to 90 days.

Treatment of existing stretch marks: StrataMark should be used for at least 60 to 90 days (24 hours a day/7 days a week). Continued use is recommended until no further improvement is seen. Severe and/or older stretch marks may need longer treatment.

Dosage and administration

StrataMark gel is an advanced formulation that requires **substantially less product** per application than typical creams or gels.

StrataMark 1.75oz (50g) is enough to treat an area of 12x12 inch (30x30 cm) for 30 days.



How supplied:

StrataMark 1.75oz (50g) tube (73661-423-50)

Additional prescribing information

Therapeutic group: gel formulation for the management of Striae Distensae (stretch marks).

Pharmaceutical form: rapidly drying, non-sticky, transparent gel formulation.

Description: When used as directed, StrataMark dries to form a thin, flexible and protective layer, that is gas permeable and waterproof which hydrates and protects stretch marks, allowing the skin to normalize the collagen synthesis cycle.

Warnings: For external use only. StrataMark should not be applied to third degree burns or to open wounds. StrataMark should not be placed in contact with eyes. StrataMark should not be applied over other skin treatments without the advice of your physician. StrataMark may stain clothing if not completely dry. 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. 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.

Contraindications: Do not administer to patients with known hypersensitivity to the ingredients of this product.

Side effects: At the time of producing this material, no adverse effects have been reported with the use of StrataMark.

Drug interactions: None known.

Use in specific populations: No specific population restrictions, StrataMark is suitable for pregnant women, breastfeeding mothers, children and people with sensitive skin.

Storage: Store at room temperature, out of direct sunlight.

StrataMark - a breakthrough in the management of stretch marks

StrataMark:

- Indicated for the management of all types of stretch marks, particularly those covering a wide surface area, resulting from pregnancy, adolescent growth spurts, weight gain or loss, or bodybuilding
- Softens and flattens raised and depressed stretch marks
- Relieves itching and discomfort of stretch marks
- Reduces redness and discoloration associated with stretch marks
- Suitable for pregnant women, breastfeeding mothers, children and people with sensitive skin
- Is inert, contains no alcohol, parabens or fragrances



To attend Educational Webinars, request samples, or if you have questions about Stratpharma products, prescriptions, supply, etc. contact us at our San Diego Headquarters:

619-930-5788 or customerservice@us.stratpharma.com

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us.stratamark.net

Ingredients: Dimethylpolysiloxane, dihydroxysiloxane and alkylmethylsiloxane.

References: 1. Osman, H., et al. (2008). *BJOG*, 115(9), pp. 1138-1142. 2. Cho, S., et al. (2006). *J of the European Academy of Dermatology and Venerology*, 20(9), pp. 1108-1113. 3. Viennet, C., et al. (2005). *Archives of dermatological research*, 297, pp. 10-17. 4. Rotsztein, H., et al. (2010). *Advances in Medical Sciences*, 55(2), pp. 343-345. 5. Chang, AL, et al. (2004). *J of the American Academy Dermatology*, 51(6), pp. 881-885. 6. Lee, KS, et al. (1994). *Clinical and experimental dermatology*, 19(4), pp. 285-288. 7. Klehr, N. (1979). *Acta dermato-venereologica. Supplementum*, 59(85), pp. 105-108. 8. Hildago, LG. (2002). *American J of Clinical Dermatology*, 3(7), pp. 497-506. 9. Atwal, GS, et al. (2006). *British J of Dermatology*, 155, pp. 965-969. 10. Elsaie, ML, et al. (2009). *Dermatologic Surgery*, 35(4), pp. 563-573. 11. Rangel, O., et al. (2001). *Advances In Therapy*, 18(4), pp. 181-186. 12. Cho, SB, et al. (2010). *J of Cosmetic and Laser Therapy*, 12, pp. 118-119. 13. Buchanan, K., et al. (2010). *International Journal of Gynaecology and Obstetrics*, 108, pp. 65-68. 14. McDaniel, DH. (2002). *Dermatologic Clinics*, 20(1), pp. 67-76. 15. Bertin, C., et al. (2013). *Skin Research and Technology*, 0, pp. 1-6. 16. Al-Himdani, S., et al. (2014). *British J of Dermatology*, 170, pp. 527-547. 17. Chan, KY, et al. (2005). *Plastic and Reconstructive Surgery*, 116(4), pp. 1013-1020. 18. Malkova, S. (2014). *New EU Magazine of Medicine*, 1-4/4, pp. 1-7. 19. Hughes, CD, Hedges, A. (2018). *Australasian Journal of Dermatology*, 60(1), pp. 78-80.