Strataderm®

scar therapy gel

For professional scar therapy



www.strataderm.com

Heal Better™
Stratpharma
Australia

The impact of abnormal scarring

For patients, scars are among the most common and **frustrating** results after a skin injury[1] (i.e. surgery, accident, disease) and can have a **physical** as well as a **psychological impact**.[2]

They often cause:

- Severe itching, tenderness and pain
- Disruption of daily activities
- Sleep disturbance, anxiety, depression
- Post-traumatic stress reactions
- Loss of self-esteem, stigmatisation
- Diminished quality of life

Psychological effects of scarring are not related to the severity of the scar[3]

Current scar therapy options

Invasive scar therapy options can be painful and include surgery, steroid injections, cryotherapy, laser and other energy-based devices.

The majority of **non-invasive** options have poor evidence or a placebo effect. They include massage therapy and a large number of different cosmetic creams, oils and lotions.[2]

Invasive	**Non-invasive**	**Other treatments** (no medical evidence of efficacy)
Surgery	Self-drying silicone gels (e.g. Strataderm)	Topical vitamin E cream (and other moisturisers)
Steroid injections	Silicone gel sheeting	Plant extract creams
Radiation therapy	Pressure garments	Oils and lotions
Cryotherapy	Topical steroids	Traditional remedies (bees wax, animal fats)
Laser therapy	Silicone based creams and oils	Camouflage and make-up
Dermabrasion	Massage therapy, water pressure	No treatment

Silicone gel is the only non-invasive option for which evidence-based recommendations have been made.[4]



Strataderm® – first-line scar therapy

Silicone gels (Strataderm) are recommended as the **gold standard, first-line non-invasive therapy** for the prevention and treatment of abnormal scars.[5,6]

Strataderm is a gel that dries to form a Silicone Gel Sheet (SGS) with **once per day application***.

Strataderm® indications

Strataderm is used for the prevention and treatment of abnormal and excessive scar formation. Strataderm was developed for the use on all types of scars, both old and new, including those resulting from:

- General and cosmetic surgery
- Trauma
- Chronic wounds
- Burns
- Bites
- Acne and other diseases of the skin

Why Strataderm® is an innovative product

Strataderm is a rapidly drying, transparent silicone gel formulation for the treatment of scars, both old and new.



FILM-FORMING, FLEXIBLE, FULL CONTACT

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



ABNORMAL SCAR PREVENTION AND TREATMENT

Strataderm helps to normalise the collagen synthesis cycle, producing a normal mature scar.



SOFTENS AND FLATTENS

Strataderm softens and flattens raised scars.



SYMPTOMATIC RELIEF

Strataderm relieves itching and discomfort of scars.



REDUCES REDNESS AND DISCOLOURATION

Strataderm reduces redness and discolouration associated with scars.



EASY TO USE

Strataderm is applied once daily*. Strataderm is suitable for all areas of the skin, including exposed areas like the face and neck as well as joints and hairy areas without the need for shaving.



NON-REACTIVE

Strataderm is inert, has no measurable pH, and contains no alcohol, parabens or fragrances, making it suitable for children, pregnant women, breastfeeding mothers and people with sensitive skin.



COMPATIBLE

Once dry, Strataderm can be covered by sunscreen, cosmetics, pressure garments or casts.

*Please refer to the Patient Information Leaflet (PIL)

Strataderm® – proven clinical efficacy

A 153-pediatric patient study conducted in Australia investigated the efficacy of Strataderm versus pressure garment and combined therapy for the treatment of post-burn injury scars.[7]

Wiseman, J., et al. (2019). 'Effectiveness of topical silicone gel and pressure garment therapy for burn scar prevention and management in children: a randomized controlled trial', Clinical Rehabilitation, doi: 10.1177/0269215519877516.



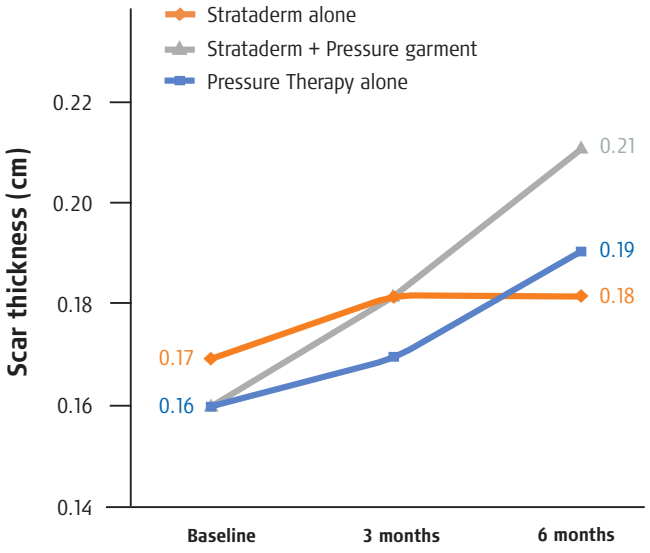
n=51 in the Strataderm group

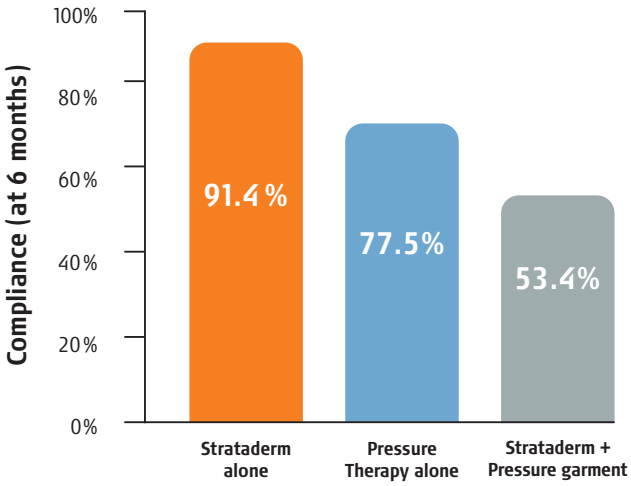


n=49 in the pressure garment therapy group



n=53 in the combined intervention group





Strataderm and pressure garments were confirmed, with statistical significance, to have the same clinical efficacy in the prevention and treatment of post-burn scar.[7]

Strataderm has less adverse effects, is easier to use and has better patient compliance compared to pressure garments.[7]

At 6 months, caregivers and observers using Strataderm alone, reported **better patient compliance, improving overall scar appearance and health-related quality of life** compared to pressure garment alone and combined group.[7]

Strataderm was reported **easier to use** compared to pressure garment therapy alone or combined therapy, where reduced intervention adherence and satisfaction were reported.[7]

Less adverse effects such as skin irritation or wound breakdown were observed in the Strataderm group compared to pressure garment group.[7]

Clinical results with Strataderm®

Widespread hypertrophic scar after deep thermal contact burn – face[8]

Age of scar before treatment: 2 months. Age of patient: 6 months old.



Start of treatment with Strataderm



After 5 months of treatment with Strataderm

After 1 month of treatment with Strataderm, a reduction in pruritus, oedema and erythema was observed. The colour of the scar was lighter, its surface was smoother.

After 5 months of scar treatment (8 months post-trauma), the postburn erythema had completely resolved, and the scars were smaller and softer. An important reduction of the deformation of the right side of the top lip was also visible.

Linear hypertrophic scar after nevus extraction – chest[9]

Age of scars before treatment: 14 months.
Left scar remained untreated, right scar treated for 2 months.

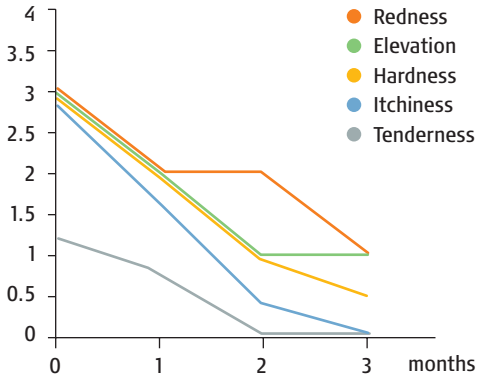


Start of treatment with Strataderm



After 2 months of treatment with Strataderm

3 months treatment



Linear hypertrophic scar – head[9]

Age of scar before treatment: 2 weeks.

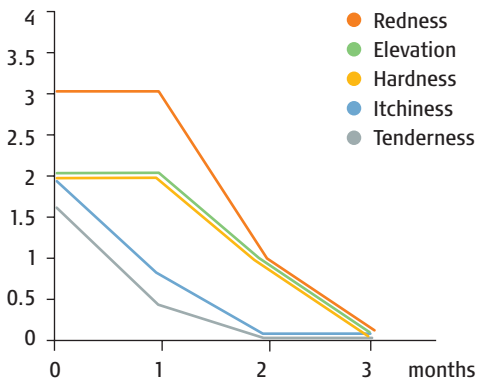


Start of treatment with Strataderm



After 3 months of treatment with Strataderm

3 months treatment



Mode of action

Hydration: Strataderm is semi-occlusive which allows the skin to breathe and remain hydrated. Strataderm restores the barrier function of the stratum corneum and reduces Trans-Epidermal Water Loss (TEWL). Better hydration helps to achieve a softer, smoother and flatter scar.[5]

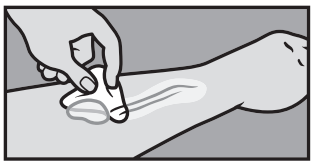
Protection: Strataderm forms a durable, flexible and waterproof sheet. It does not penetrate into the epidermis or dermis.[10] Strataderm protects the scarred site from microbial and chemical invasion. The protected environment helps to normalise the level of collagen production.

Modulation: Abnormal scar formation is associated with an abnormal proliferation of fibroblasts. It is suggested that silicone gel (like Strataderm) treats and prevents hypertrophic scar tissue, which contains histologically normal fibroblasts, by modulating expression of growth factors such as bFGF. Correcting a deficiency or overabundance of growth factors that orchestrate the tissue repair process has a favorable influence on wound healing and scar formation.[11]

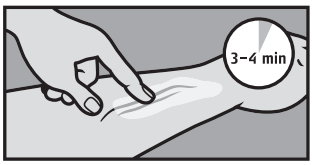
Directions for use



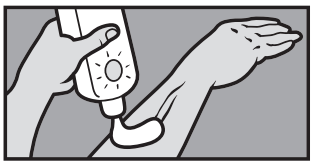
1. Ensure that the scar is clean and dry.



2. Apply a **very thin layer** of Strataderm to the scar and allow to dry. When applied correctly, Strataderm should be dry in **3–4 minutes**.



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



4. Once dry, Strataderm can be covered by sunscreen, cosmetics, pressure garments or casts.

Additional directions

- Strataderm should be applied **once daily**, or twice daily to exposed areas or as required to maintain contact with the affected surface.
- For best results Strataderm should be maintained in continuous contact with the skin (24 hours a day/7 days a week).
- Strataderm is recommended as **minimum treatment of 60–90 days**. Larger and older scars may take longer. Continued use is recommended until no further improvement is seen.
- Strataderm **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, Strataderm may stain clothing. If staining occurs, dry cleaning should be able to remove it without damaging the fabric.

Strataderm® and other products

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

Strataderm can be used in conjunction with other invasive scar treatment options to improve overall results, including surgical excision and resuturing, intralesional injections and pressure garments.

IMPORTANT

Because Strataderm is semi-occlusive:

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

How much Strataderm® is needed?

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



Strataderm 5g
is enough to treat a 2–3 cm linear scar for over 90 days



Strataderm 10g
is enough to treat a 5–7 cm linear scar for over 90 days



Strataderm 20g
is enough to treat a 10–14 cm linear scar for over 90 days



Strataderm 50g
is enough to treat an area of 6×12 cm for over 90 days

Stratamed and Strataderm – the complete combination for post-procedure care

Step 1 – Stratamed:
Faster healing and early abnormal scar prevention

- A film-forming, flexible, full contact wound dressing
- Can be applied immediately after suturing or on open wounds
- Promotes a moist environment for faster wound healing[12]
- Allows abnormal scar prevention to begin earlier than ever before (before suture removal)

Stratamed®

advanced film-forming wound dressing



www.stratamed.com

Strataderm®

scar therapy gel



Step 2 – Strataderm:
For the treatment of abnormal scars, both old and new

- Prevents abnormal and excessive scar formation
- Softens and flattens raised scars
- Relieves the itching and discomfort of scars
- Reduces redness and discolouration associated with scars

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Caution: Always read the label. Use only as directed. For external use only. Strataderm should not be applied on third degree burns or to open wounds. Strataderm should not be placed in contact with mucous membranes or the eyes. Strataderm should not be applied over topical medications unless advised by your physician. Strataderm 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. Strataderm does not require special disposal methods. Please follow your local disposal regulations. **Ingredients:** Polydimethylsiloxanes, siloxanes, alkylmethyl silicones.

References: 1. Atiyeh, BS. (2007). Aesthetic Plastic Surgery, 31, pp. 468–492, doi: 10.1007/S00266-006-0253-Y. 2. Bayat, A., et al. (2003). BMJ, 326, pp. 88–92, doi: 10.1136/bmj.326.7380.88. 3. Bayat, A., et al. (2006). British J Hospital Medicine, 67(8), pp. 634–639. 4. Mustoe, TA, et al. (2002). Plastic Reconstructive Surgery, 110, pp. 560–571. 5. Mustoe, TA. (2008). Aesthetic Plastic Surgery, 32, pp. 82–92. 6. Gold, MH, et al. (2014), Dermatologic Surgery, 40(8), pp. 825–831. 7. Wiseman, J., et al. (2019). Clinical Rehabilitation, doi: 10.1177/0269215519877516. 8. Marini, L., Odendaal, D., Smirnyi, S. (2017). Dermatologic Surgery, 43, pp. 85–90. 9. Data on file, 2010 (Dr. A. Irwin study). Stratpharma AG. 10. Fulton, JE. (1995). Dermatologic Surgery, 21 pp. 947–951. 11. Hanasono, MM, et al. (2004). Archives of Facial Plastic Surgery, 6, pp. 88–93. 12. Sandhofer, M., Schauer, P. (2012). Skinmed, 10(6), pp. S1–S7.

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Strataderm is Class I Medical Device, TGA Registered
Stratamed is Class IIa Medical Device, TGA Registered

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