

Rx Only
For topical use only
73661-424-20

ADVANCED FORMULATION
Strata **triz**[®]
scar therapy gel

For professional scar therapy



 **Stratpharma**
Switzerland

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

The impact of abnormal scarring

For patients, scars are among the most common and **frustrating** results after a skin injury¹ (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, stigmatization
- Diminished quality of life

Psychological effects of scarring are not related to the severity of the scar³

Current scar therapy options

Invasive scar therapy options can be painful and include surgery, steroid injections, cryotherapy, laser and other energy-based devices. 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 lotion.²

Invasive	Non-invasive	Other treatments (no medical evidence of efficacy)
Surgery	Silicone gel (e.g. StrataTriz)	Topical vitamin E cream (and other moisturizers)
Steroid injections	Pressure/compression therapy	Plant extract creams
Radiation therapy	Topical steroids	Oils and lotions
Cryotherapy	Counselling	Massage therapy
Laser therapy	Polyurethane patches	Camouflage and make-up
Dermabrasion	Acrylic casts	No treatment

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



StrataTriz – first-line scar therapy

Silicone gels (StrataTriz) are recommended as the gold standard, first-line, non-invasive therapy for the management and treatment of abnormal scars.^{5,6}

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

StrataTriz indications

StrataTriz is intended to be used under the direction of healthcare practitioners in the management of scars.

StrataTriz is indicated for the use on all types of scars including those resulting from:

- Surgery
- Trauma
- Chronic wounds
- Burns
- Bites
- Acne and other diseases of the skin.

Why is StrataTriz an innovative product?

FILM-FORMING, FLEXIBLE, FULL CONTACT
StrataTriz dries to form a thin, transparent and flexible protective film that ensures constant contact with the scar (24 hours a day/7 days a week).

SCAR MANAGEMENT
StrataTriz helps to normalize the collagen synthesis cycle, producing a normal mature scar.

SOFTENS AND FLATTENS
StrataTriz softens and flattens raised scars.

SYMPTOMATIC RELIEF
StrataTriz relieves itching and discomfort.

REDUCES REDNESS AND DISCOLORATION
StrataTriz reduces redness and discoloration.

CONVENIENT AND EASY TO USE
StrataTriz is applied once daily*. StrataTriz 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
StrataTriz is inert, contains no alcohol, parabens or fragrances, making it suitable for children, pregnant women, breastfeeding mothers and people with sensitive skin.

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

Mode of action

Hydration: StrataTriz is gas permeable and waterproof, which allows the skin to breath and remain hydrated. StrataTriz 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

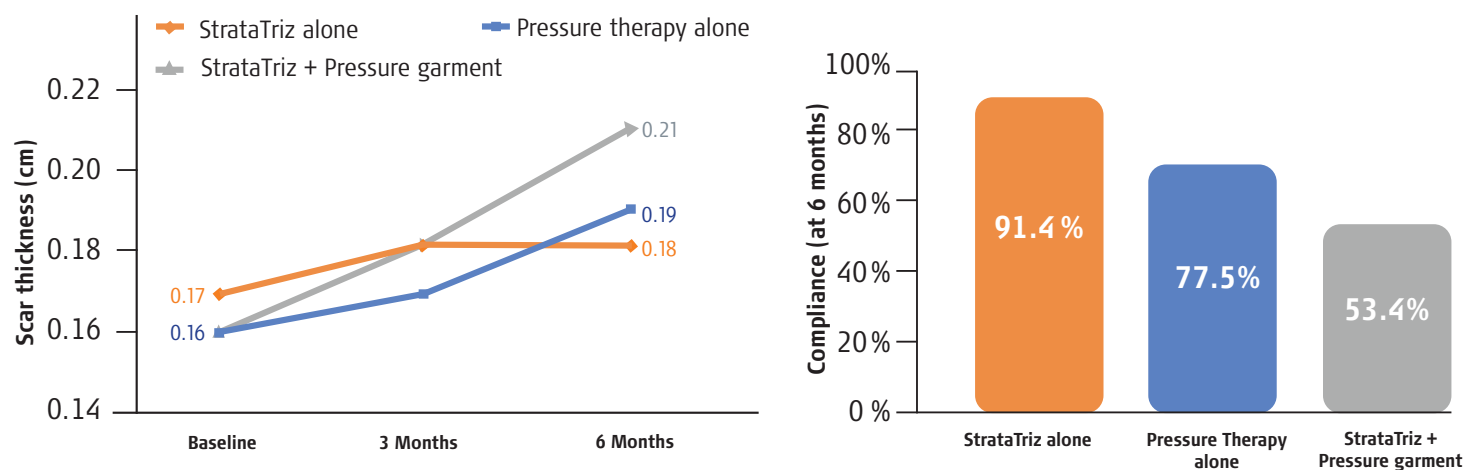
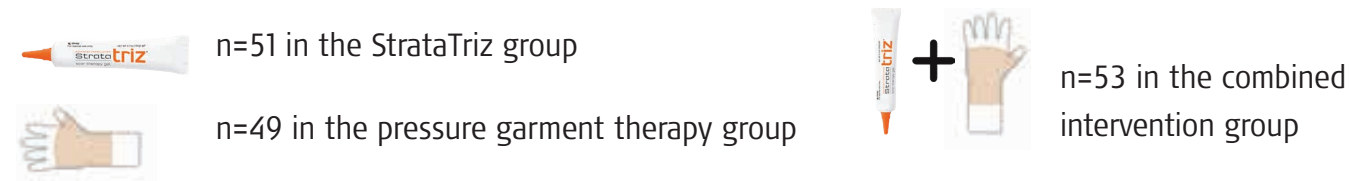
Protection: StrataTriz forms a durable, flexible and waterproof sheet. It does not penetrate the epidermis or dermis.⁷ StrataTriz protects the scarred site from microbial and chemical invasion. The protected environment helps to normalize the level of collagen production.

Modulation: Abnormal scar formation is associated with an abnormal proliferation of fibroblasts. It is suggested that silicone gel (like StrataTriz) 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.⁸

StrataTriz – proven clinical efficacy

A 153-pediatric patient study conducted in Australia investigated the efficacy of StrataTriz versus pressure garment and combined therapy for the treatment of post-burn injury scars.⁹

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* Available at: doi 10.1177/0269215519877516.



At 6 months, caregivers and observers using StrataTriz alone, reported **better patient compliance, improving overall scar appearance and health-related Quality Of Life** compared to pressure garment alone and combined group.⁹

StrataTriz was reported **easier to use** compared to pressure garment therapy alone or combined therapy, where reduced intervention adherence and satisfaction were reported.⁹

Less adverse effects such as skin irritation or wound breakdown were observed in the StrataTriz group compared to pressure garment group.⁹

Clinical results with StrataTriz

Widespread hypertrophic scar after deep thermal contact burn – face¹⁰

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



Start of StrataTriz treatment

5 months of using StrataTriz

After 1 month of treatment with StrataTriz, a reduction of pruritus, edema and erythema was observed. The color of the scar was lighter, its surface was smoother.

After 5 months of scar treatment (8 months post-trauma), the post-burn 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 – chest¹¹

Age of scars before treatment: 14 months

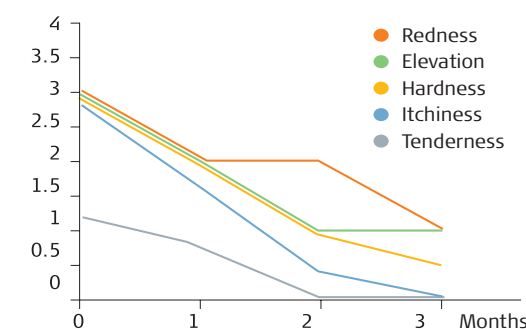
Left scar remained untreated, right scar treated for 2 months



Start of StrataTriz treatment

2 months of using StrataTriz

3 months treatment



Linear hypertrophic scar – head¹¹

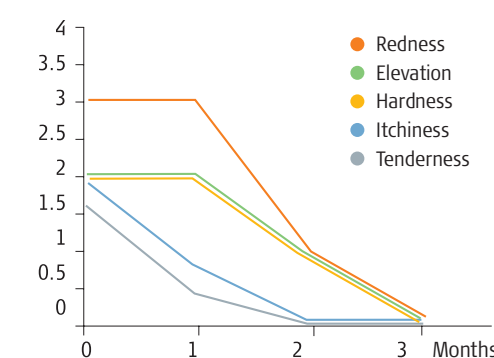
Age of scar before treatment: 2 weeks



Start of StrataTriz treatment

3 months of using StrataTriz

3 months treatment



Dosage and administration

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

StrataTriz 0.7 oz (20 g) is enough to treat an area of 5 × 5 inch (12 × 12 cm) twice per day for 30 days.



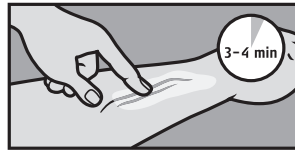
How supplied

StrataTriz 0.70 oz (20g) tube (73661-424-20)

Directions for use



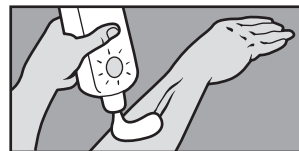
1. Ensure that the scar is clean and dry.



2. Apply a **very thin layer** of StrataTriz to the scar and allow to dry. When applied correctly, StrataTriz 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, StrataTriz can be covered by sunscreen, cosmetics, pressure garments or casts.

Additional directions

- StrataTriz should be applied once daily, or twice daily to exposed areas or as required to maintain contact with the affected surface.
- For best results StrataTriz should be maintained in continuous contact with the skin (24 hours a day/7 days a week).
- StrataTriz 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.
- StrataTriz 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, StrataTriz 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.



StrataTriz and other products

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

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

IMPORTANT

Due to StrataTriz's semi-permeable nature:

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

Additional prescribing information

Therapeutic group: transparent gel formulation for the management of scars, both old and new.

Pharmaceutical form: transparent gel formulation.

Description: When used as directed StrataTriz dries to form a protective layer that is gas permeable and waterproof which hydrates and protects scars from chemical and microbial invasion, allowing scars to normalize the collagen synthesis cycles, producing a normal mature scar.

Warnings: For external use only. StrataTriz should not be applied on third degree burns or to open wounds. StrataTriz should not be placed in contact with mucous membranes or the eyes. StrataTriz should not be applied over topical medications unless advised by your physician. StrataTriz 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 StrataTriz.

Drug interactions: None known.

Use in specific populations: No specific population restrictions, StrataTriz is suitable to use on infants, children, people with sensitive skin, during pregnancy and whilst breastfeeding.

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

Filling a StrataTriz prescription

If StrataTriz will be picked up by the patient in an institutional pharmacy associated with your clinic, please share the tear sheet with the patient so they can receive the lowest co-pay possible.

Otherwise, StrataTriz can be filled by Truepill pharmacy. Please share the tear sheet with the patient and follow the instructions below.

Your patient will receive StrataTriz as you prescribed it with free delivery from Truepill pharmacy.

Truepill

We are processing your prescription. What's next?

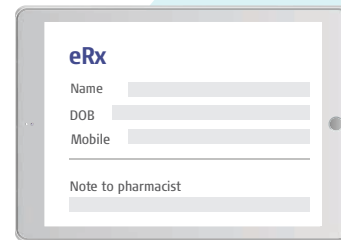
1

Send script to Truepill

- eRx: Truepill (Hayward, CA) or NCPDP: 5660091
- Fax: 518-734-0053
- Verbal: 650-353-5495 | 855-910-8606

To minimize callbacks, include:

- Patient's current mobile number
- Patient's email
- Patient insurance information
- Tried/failed meds or chart notes
- Allergies
- ICD-10 code



2

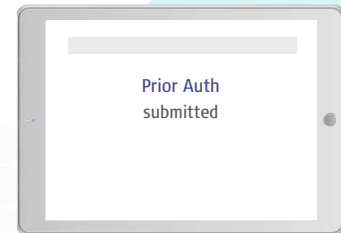
Provide tear sheet to patient

Patient will receive a phone call or text with instructions on how to proceed with the prescription.

3

Submit any prior auths in CoverMyMeds

with the key provided by Truepill. In the event CoverMyMeds does not process PA the pharmacy will notify you.



Questions about prescription? Contact Truepill's HCP support team at: 650-353-5495 | 855-910-8606 or operations_support@truepill.com

us.stratatriz.com

Ingredients: Polydimethylsiloxane, hydroxylsiloxane and alkyl siloxane.

References: 1. Atiyeh, B.S. (2007), Aesthetic Plastic Surgery, 31(5), pp. 468-492. 2. Bayat A et al. (2003), British Medical J, 326, pp. 88-92. 3. Bayat A et al. (2006), British J of Hospital Medicine, 67(8), pp. 634-639. 4. Mustoe TA et al. (2002), Plastic and reconstructive surgery, 110(2), pp. 560-571. 5. Mustoe TA. (2008), Aesthetic Plastic Surgery, 32(1), pp. 82-92. 6. Gold MH, et al. (2014), Dermatologic Surgery, 40(8), pp. 825-831. 7. Fulton JE. (1995), Dermatologic Surgery, 21, pp. 947-951. 8. Hanasono MM, et al. (2004), Archives of facial plastic surgery, 6(2), pp. 88-93. 9. Wiseman, J et al. (2019), Clinical Rehabilitation, 34(1), pp. 120-131. 10. Marini L, et al. (2017), Dermatologic Surgery, 43, pp. 85-90. 11. Data on file, 2010 (Dr. A. Irwin study). Stratpharma AG.

CE Class I Medical Device
FDA Listed

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Distributed by: Mamel Pharmaceuticals LLC Charleston, SC 29403, U.S.A. 1-833-788-0312

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