℞ Only
For topical use only
73661-422-20

ADVANCED FORMULATION
Strata grt®
for chronic and hard to treat wounds

Advanced gel for chronic and hard to treat wounds

Stratpharma
Switzerland

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

Chronic and hard to treat wounds

While most wounds heal without further assistance, chronic and hard to treat wounds are a **significant medical problem** for an increasing number of patients. They demand specialty and ongoing care, as well as significant resources in their treatment. Even with the best medical care, chronic and hard to treat wounds can be **life threatening** as they pose serious risks of infection and can cause significant discomfort, stress and a marked **reduction in the patients Quality of Life**.

In the United States, it is estimated that chronic non-healing wounds affect as many as 9 million people, resulting in **severe emotional and physical trauma** for patients and their families.[1-2] Chronic wounds will continue to be an increasingly persistent problem due to the increasing proportion of elderly population along with the diabetic and obesity epidemic.[3]

Access to and the delivery of advanced wound care represents a major challenge for institutions, Healthcare Processionals and sufferers of chronic wounds. For patients suffering from these wounds the profound **physical effects** are often accompanied by a **psychological impact**, such as loneliness, separation from an active social life, and depression. These psycho-social stressors further worsen healing outcomes.[4]

Current treatment and Challenges

There are many options currently available for the treatment of chronic wounds following significant advances in technologies from recent years. There still remains, however, many challenges in successfully treating these wounds, such as antibiotic resistance, infection relapse and the use of non-optimal wound dressings.[5-7]

Many **physical wound dressings** are only suitable for wounds on flat surfaces. As a result, these physical wound dressings **do not enable** full surface contact with a lot of wounds (i.e. wounds near joints, on highly contoured areas, deep or tunneling wounds). The adhesive parts of these dressings have also shown to cause **allergic reactions** leading to **delays or complications** in the wound healing outcome.[8-11]

Additionally, physical dressings can also limit mobility thereby restricting patients' movements affecting their **daily activities and quality of life**. The properties of these dressings may not be ideal for patients to apply at home and need additional nursing care for its application and maintenance.[12]

An ideal wound care product should be flexible, gas-permeable, transparent and easy to apply on all wound surfaces. It should also support the moist wound healing environment, prevent infection and reduce side effects.[13]

StrataGRT indications

StrataGRT is intended to be used under the direction of healthcare practitioners in the management of chronic and hard to treat wounds.

StrataGRT is indicated for use on all types of chronic and acute wounds including:

chronic wounds:
- venous (stasis) ulcers
- neuropathic (diabetic) ulcers
- arterial (ischemic) ulcers
- pressure (decubitus) ulcers

acute wounds:
- post traumatic wounds
- burns
- skin tears
- surgery
- wound dehiscence

StrataGRT may be directly applied to fresh incisions and excisions, open wounds and compromised skin surfaces.

Why is StrataGRT gel an innovative product?

FILM-FORMING, FLEXIBLE, FULL CONTACT
StrataGRT gel dries to form a thin and flexible wound dressing that ensures full constant contact with the skin.

FASTER WOUND HEALING
StrataGRT promotes a moist healing environment leading to faster re-epithelialization.[14-15]

PROTECTION
StrataGRT is bacteriostatic, it protects the wound from chemical and microbial invasion, while reducing the risk for contact dermatitis.

HYDRATION AND GAS PERMEABILITY
StrataGRT is semi-permeable, which allows the skin to breathe and remain hydrated.

SECONDARY DRESSINGS
StrataGRT can be used with or without a secondary protective dressing, in combination with other wound care therapies and topical agents.

HARD TO TREAT AREAS
StrataGRT is suitable for exposed areas like the face and neck as well as joints and hairy areas without the need for shaving.

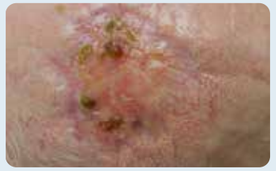
NON-REACTIVE
StrataGRT is non-reactive, it has no measurable pH, and contains no steroids, alcohols, parabens or fragrances making it suitable for infants, children, people with sensitive skin, during pregnancy and while breastfeeding.

EASY TO USE
StrataGRT is easy to apply without the need for removal before re-application and can be used by patients at home.

Clinical evidence*

Successful Treatment of Nonhealing Scalp Wounds[16-18]

4 months after surgery, start of treatment with StrataGRT



After 1 week of treatment with StrataGRT

2 years after surgery, start of treatment with StrataGRT

After 5 weeks of treatment with StrataGRT

Monk, E et al. (2014). 'Successful Treatment of Nonhealing Scalp Wounds Using a Silicone Gel', *Dermatologic Surgery*, 40 (1), pp. 76–79.

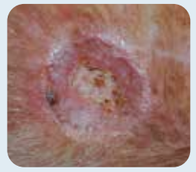
"We believe that this gel was a major reason why all patients had improvement and healing of their scalp wounds after a prolonged period of nonhealing."

"StrataGRT for our patients uses the unique properties of film-forming gels in a formulation that may be ideal for these wounds."

Prof. Anthony Benedetto, MD, DO, FACP, Philadelphia, USA

Start of treatment with StrataGRT

After 1 week of treatment with StrataGRT



After 6 weeks of treatment with StrataGRT

Marini, L et al. (2017). 'Importance of Scar Prevention and Treatment—An Approach From Wound Care Principle', *Dermatologic Surgery*. 43(1), pp. 85-90.

- StrataGRT on chronic wounds provides an effective "healing boost" to biologically inactive granulation tissue inducing re-epithelialization even after only 1 week of treatment.
- StrataGRT is effective for challenging persistent ulcerative lesions secondary to surgery followed by partial-thickness skin grafts.
- StrataGRT prevents tissue maceration to the wound's surrounding skin, allowing less frequent dressing changes, although secondary dressings were not required in any of the published cases.

Before treatment

Immediately after debridement of the large crust. Start treatment with StrataGRT

After 2 weeks of treatment with StrataGRT

Uva, L et al. (2015). 'Erosive pustular dermatosis successfully treated with a novel silicone gel Case Report'. *International Journal of Dermatology*, 55(1), pp. 89–91.

*The publications and case series shown here may be with products under different Stratpharma brand names in different countries (such as Stratamed). All cases are treated with the StrataGRT product as it is known in the USA.

Clinical evidence for different indications

Start of treatment with StrataGRT

After 14 days of treatment with StrataGRT

After 21 days of treatment with StrataGRT

Ulcus crusis venosum (severe)[19]
Location: Lower leg, >90 days open

Dr. Strohal, Federal Academic Teaching Hospital. Feldkirch, Austria.

Start of treatment with StrataGRT

After 18 days of treatment with StrataGRT

After 31 days of treatment with StrataGRT

Diabetic Foot syndrome[20]
Ulcus cruris venosum

Madrid, Spain.

Start of treatment with StrataGRT

After 6 days of treatment with StrataGRT

After 9 days of treatment with StrataGRT

Second degree burn [21]
Location: Foot

Hospital Municipal de Quemados. Buenos Aires, Argentina.

Start of treatment with StrataGRT

After 2 months of treatment with StrataGRT

Squamous cell carcinoma (SCC)[22]
Surgical excision and skin flap surgery for reconstruction.

Dr.Cubiro, Hospital de Sant Pau. Barcelona, Spain.

Start of treatment with StrataGRT

After 7 days of treatment with StrataGRT

Full thickness donor site wound[23]

Data on file. Stratpharma AG.

Dosage and administration

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

StrataGRT 0.7oz (20g) is enough to treat an area of 5x5 inch (12×12cm) twice per day for 30 days.

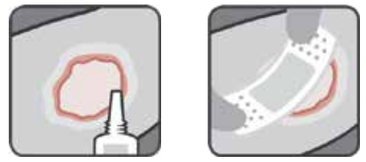
Directions for use

- Ensure that the affected superficial area is cleaned before each application.
- Gently pat dry as much exudate or wound fluid from the area as possible prior to gel application.

On wounds <u>not requiring</u> a secondary dressing

1. Apply a **thin layer** of StrataGRT to the affected area and allow the gel to dry.
2. When applied correctly to exposed areas, StrataGRT should be **dry in 5-6 minutes**. 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.
3. StrataGRT should be applied **twice daily** to exposed areas or as required to maintain contact with the affected surface.
4. If StrataGRT has been removed by washing, it should be **re-applied**.

On wounds <u>requiring</u> a secondary dressing



1. Apply a **thin layer** of StrataGRT then cover with the secondary dressing.
2. **Drying is not necessary.**
3. StrataGRT should be reapplied when **changing the dressing or checking the wound progress**, or as advised by the physician.

Additional directions

- For best results StrataGRT should be maintained in **continuous contact** with the skin (24 hours a day/7 days a week). StrataGRT may be re-applied **more often** to ensure constant contact with the skin, or to reduce symptoms.
- StrataGRT can be applied **directly** to the wound, using the finger, Q-tip etc.
- StrataGRT will **not absorb exudate or wound fluid**. The film formed by StrataGRT will not prevent the fluid from escaping from the wound.
- StrataGRT may be used in combination with absorbent dressings. Apply StrataGRT directly to the wound or to the contact side of the secondary dressing.
- Applying StrataGRT on the wound edges will help prevent maceration.
- If not completely dry, StrataGRT 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.

StrataGRT and other products

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

IMPORTANT:

Due to StrataGRT's semi-permeable nature:

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

Additional prescribing information

Therapeutic group: Wound dressing for chronic and hard to treat wounds.

Pharmaceutical form: Occlusive, non-resorbable, self-drying and transparent gel.

Description: When used as directed, StrataGRT dries to form a protective layer that is gas permeable and waterproof which hydrates and protects chronic and hard to treat wounds. StrataGRT helps to promote a moist healing environment. This moist wound healing environment promotes faster re-epithelialization* and reduces the skin's acute inflammatory response.

Warnings: For external use only. StrataGRT should not be placed in contact with the eyes. StrataGRT should not be applied over other skin treatments without the advice of your physician. StrataGRT 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 StrataGRT.

Drug interactions: None known.

Use in specific populations: No specific population restrictions, StrataGRT is suitable for infants, children, people with sensitive skin, during pregnancy and while breastfeeding.

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

*Losi P et al. J Mater Sci Mater Med. 2012;23(9):2235-43

ADVANCED FORMULATION
Strata grt®
for chronic and hard to treat wounds

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For topical use only
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StrataGRT - advanced gel for chronic and hard to treat wounds

StrataGRT:

- Is indicated for use on all types of chronic and acute wounds
- Promotes a moist healing environment leading to faster re-epithelialization
- Is bacteriostatic, reducing the risk of infection
- Is semi-permeable, which allows the skin to breathe and remain hydrated.
- Is inert, contains no alcohol, parabens or fragrances
- Is easy to apply on all wounds surfaces without the need for removal before re-application

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
Stratpharma Inc, 7676 Hazard Center Drive, Suite 880, San Diego, CA 92108 USA

us.stratagrt.com

Ingredients: Linear dimethylpolysiloxanes, octamethyltrisiloxane and siloxane resin. STERILE UNTIL OPENED.

References: 1. Chandan, K., Sen. (2019). *Advances in Wound Care*, 8(2), pp. 39-48. 2. Järbrink, K., et al. (2017). *Systematic Reviews*, 6, pp. 15. 3. Situm, M., et al. (2014). 68, Suppl 1, pp. 5-7. 4. Atkin, L. (2019). 1(24), Sup9, pp. S26-S32. 5. Han, G., Ceilley, R. (2017). *Advances in Therapy*, 34(3), pp. 599-610. 6. ECDC calls for continued action to address antimicrobial resistance in healthcare settings. European Centre for Disease Prevention and Control, availabe online at: https://www.ecdc.europa.eu/en/news-events/ecdc-calls-continued-action-address-antimicrobial-resistance-healthcare-settings. 7. Wynn, R. (2017). available online at: https://www.wolterskluwercdi.com/blog/ades-from-antibiotic-exposure/. 8. Whitney, J., et al. (2006). *Wound Repair Regen*, 14, pp. 663-679. 9. Steed, DL, et al. (2006). *Wound Repair Regen*, 14, pp. 680-692. 10. Hopf, HW, et al. (2006). *Wound Repair* Regen, 14, pp. 693-710; 11. Bamberg R, et al. (2002), Wounds, 14, pp. 314-327; 12. Sood A, et al. (2014), Advances in Wound Care, 3(8), pp. 511-529; 13. Marini L. (2017), Journal of the European Academy of Dermatology *and Venereology*, 32(1), pp. 113-116. 14. Losi, P., et al. (2012). *J Mater Sci Mater Med*, 23(9, pp. 2235-43. 15. Sandhofer, M., Schauer, P. (2012). *SKINmed*, 10, S1-S7. 16. Monk, E., Benedetto, EA, Benedetto, AV (2014). *Dermatologic Surgery*, 40(1), pp. 76-79. 17. Marini, L., Odendaal, D., Smirnyi. S. (2017). *Dermatologic Surgery*, 43, S85-S90. 18. Uva, L., et al. (2015). *International Journal of Dermatology*, 55(1), pp. 89-91. 19. Data on file, 2016 (Federal Academic Teaching Hospital. Feldkirch, Austria). Stratpharma AG. 20. Data on file, 2010 (Madrid, Spain). Stratpharma AG. 21. Data on file, 2016 (Hospital Municipal de Quemados. Buenos Aires, Argentina). Stratpharma AG. 22. Data on file, 2016 (Hospital de Sant Pau. Barcelona, Spain). Stratpharma AG. 23. Data on file, Stratpharma AG.

FDA Registered
Class I Medical Device

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

Stratpharma Switzerland

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