

Rx Only
For topical use only
73661-422-20

ADVANCED FORMULATION

Strata

for chronic and hard
to treat wounds

grt[®]

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

Every time the integrity of the skin barrier is compromised, a wound is created. Wounds that heal uneventfully with time are considered **acute wounds** (i.e. surgical and traumatic wounds, abrasions, or superficial burns).¹



Wounds that have not progressed through the normal process of healing and are open for more than a month, demand specialty and ongoing care, are classified as **chronic¹ and hard to treat wounds**.

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 Quality of Life**.

For patients suffering from chronic or hard to treat 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.²

Current treatment and Challenges

There are many options currently available for the treatment of chronic wounds following significant advances in technologies from recent years. However, there are still many challenges in successfully treating these wounds.

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.⁵⁻⁸

Additionally, physical dressings can also limit mobility thereby restricting movements affecting **daily activities and quality of life**.

The properties of these dressings may not be ideal to apply at home and need additional nursing care for its application and maintenance.⁹

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, prevent infection and reduce side effects.¹⁰

Take care of your chronic wound³

- Wash your hands before and after touching your wound. It is important to prevent infection and to wash your hands regularly. You can use soap and water, or an alcohol-based hand sanitizer.
- Keep a clean and effective dressing on your wound. Dressings keep out germs and protect the wound from injury. They also help absorb fluid that drains from the wound and could damage the skin around it.
- Protect the wound from trauma or injury. Don't let anything touch it or bump it.
- If your wound is on your foot or ankle, keep it free from contamination from water washing off the upper body from a shower or bath. The wound should be kept dry or elevated in a shower to keep contaminated water from the upper body from draining over the wound.
- Eating the right foods gives your body the nutrition needed to heal.

StrataGRT – an innovative product for chronic and hard to treat wounds

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

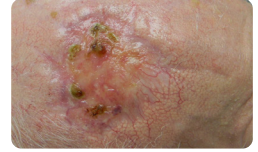
StrataGRT may be directly applied to fresh incisions and excisions, open wounds and compromised skin surfaces.

Clinical results*

Chronic wound after Mohs surgery¹¹. Location: head



4 months after surgery, start of treatment with StrataGRT



After 1 week of treatment with StrataGRT

Burn.¹² Location: foot



Start of treatment with StrataGRT



After 7 days of treatment with StrataGRT

Venus ulcer.¹³ Location: lower leg, >90 days open



Start of treatment with StrataGRT



After 14 days of treatment with StrataGRT



After 21 days of treatment with StrataGRT



FILM-FORMING, FLEXIBLE, FULL CONTACT

StrataGRT gel forms a thin, flexible film that ensures full contact with the wound.



FASTER WOUND HEALING

StrataGRT promotes a moist wound healing environment leading to faster wound healing.



PROTECTION

StrataGRT protects the wound from irritants 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.



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 alcohol, parabens or fragrances, making it suitable for infants, children, people with sensitive skin, during pregnancy and while breastfeeding.



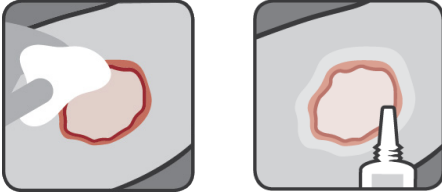
EASY TO USE

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

How to apply StrataGRT

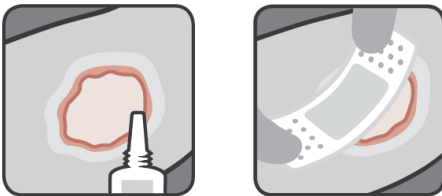
- Ensure that the affected superficial area is cleaned before each application.
- Gently pat dry as much excess exudate or wound fluid from the area as possible prior to gel application.

On wounds not requiring a secondary dressing:



- Apply a **thin layer** of StrataGRT directly to the affected area and allow the gel to dry.
- When applied correctly to the affected 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.
- StrataGRT should be applied twice daily to exposed areas or as advised by your physician.
- If StrataGRT has been removed by washing, it should be **re-applied**.

On wounds requiring a secondary dressing:



- Apply a **thin layer** of StrataGRT directly to the affected area, then cover with the secondary dressing. **Drying is not necessary**.
- StrataGRT should be reapplied when **changing the dressing or checking wound progress**, or as advised by your physician.

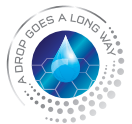
Additional directions

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

Dosage and administration

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

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



Warnings and Contraindications

Warning: For external use only. StrataGRT should not be placed in contact with the eyes. StrataGRT should not be applied over topical medications unless advised by 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.

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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 faster wound healing
- Reduces the risk of infection
- Hydrates and protects all types of wounds
- Is non-reactive, contains no alcohol, parabens or fragrances
- Is easy to apply on all wounds surfaces without the need for removal before re-application



Questions about Stratpharma products or prescriptions, contact us at our San Diego Headquarters:

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

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*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.

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

References: 1. Sen, CK. (2019). *Advances in wound care*, 8(2), pp. 39-48. 2. Atkin, L. (2019). *British J of community nursing*, 24 (9), pp. 526-532. 3. Wound Care Home Instructions, viewed 04/09/2020, <https://intermountainhealthcare.org/services/wound-care/wound-care/treatments/chronic-wound-care-home-instructions/>. 4. Robert, G. et al. (2015). *Advances in Wound Care*, 4 (9), <https://doi.org/10.1089/wound.2015.0635>. 5. Whitney, J. et al. (2006). *Wound Repair Regen*, 14, pp. 663-679. 6. Steed, DL. et al. (2006). *Wound Repair Regen*, 14, pp. 680-692. 7. Hopf, HW. et al. (2006). *Wound Repair Regen*, 14, pp. 693-710. 8. Bamberg, R. et al. (2002). *Wounds*, 14, pp. 314-327. 9. Sood, A. et al. (2014). *Advances in Wound Care*, 3(8), pp. 511-529. 10. Marini, L. (2017). *Journal of the European Academy of Dermatology and Venereology*, 32(1), pp. 113-116. 11. Monk, E. et al. (2014). *Dermatologic Surgery*, 40(1), pp. 76-79. 12. Data on file, Stratpharma AG. 13. Data on file, 2016 (Federal Academic Teaching Hospital, Feldkirch, Linz, Austria). Stratpharma AG.

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

FDA Registered

Class I Medical Device

 **Stratpharma**
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GT-US-026-3-0422