STRATAGRT- dressing, wound, occlusive
Marnel Pharmaceuticals, Inc.

StrataGRT

R_x Only

For topical use only

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

[EN] Description

StrataGRT is an occlusive, non-resorbable, self-drying and transparent gel.

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.

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

Indication for use

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.

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

StrataGRT gel is bacteriostatic and inert.

StrataGRT contains no alcohols, parabens or fragrances.

StrataGRT can be used with or without a secondary protective dressing.

StrataGRT is suitable for infants, children, people with sensitive skin, during pregnancy and while breastfeeding.

StrataGRT is intended for single patient use.

Directions for use

On first use of 0.7 oz (20 g) tubes remove the cap, cut the nozzle tip of the tube and close with the cap after use.

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.

For best results StrataGRT should be maintained in continuous contact with the skin (24 hours a day/7 days aweek).

On wounds not requiring a secondary dressing:

Apply a thin layer of StrataGRT to the affected area and allow the gel to dry.

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.

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 reapplied.

On wounds requiring a secondary dressing:

Apply a thin layer of StrataGRT then cover with secondary dressing.

Drying is not necessary.

StrataGRT should be reapplied when changing the dressing or checking the wound progress, or as advised by your physician.

How much StrataGRT do I need?

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 5X5 inch (12X12 cm) twice per day for 30 days.

Warning

- For external use only.
- StrataGRT should not be placed in contact with the eyes.
- StrataGRT should not be applied over other skin treatment 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.

STERILE UNTIL OPENED

Ingredients: Linear dimethylpolysiloxanes, octamethyltrisiloxane and siloxane resin.

How supplied:

StrataGRT 0.7 oz (20g) tube

Product Identification code:

73661-422-20

129 mm

www.us.stratagrt.com

Indications for use: StrataGRT is intended to be used under the direction of a healthcare practitioner in the management of chronic and hard to treat wounds.

Warning: For external use only. Keep out of the reach of children.

FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PRACTITIONER.

Ingredients: Linear dimethylpolysiloxanes, octamethyltrisiloxane and siloxane resin.

See package insert for full information.

us.stratagrt.com
1-833-788-0312

GR020USENBX01-0420

28 mm

73661-422-20

℞ Only
For topical use only

gel
0.7oz
20g

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

gel
0.7oz
20g

www.us.stratagrt.com

86°F STERILE R PAP
STERILE UNTIL OPENED
CE 2797

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Stratpharma AG
Aeschenvorstadt 57
CH-4051 Basel
Switzerland

Distributed by
Marnel Pharmaceuticals LLC,
Charleston, SC 29403, U.S.A.

Stratpharma Switzerland

Marnel Pharmaceuticals

40 × 16 mm

www.us.stratagrt.com

73661-422-20

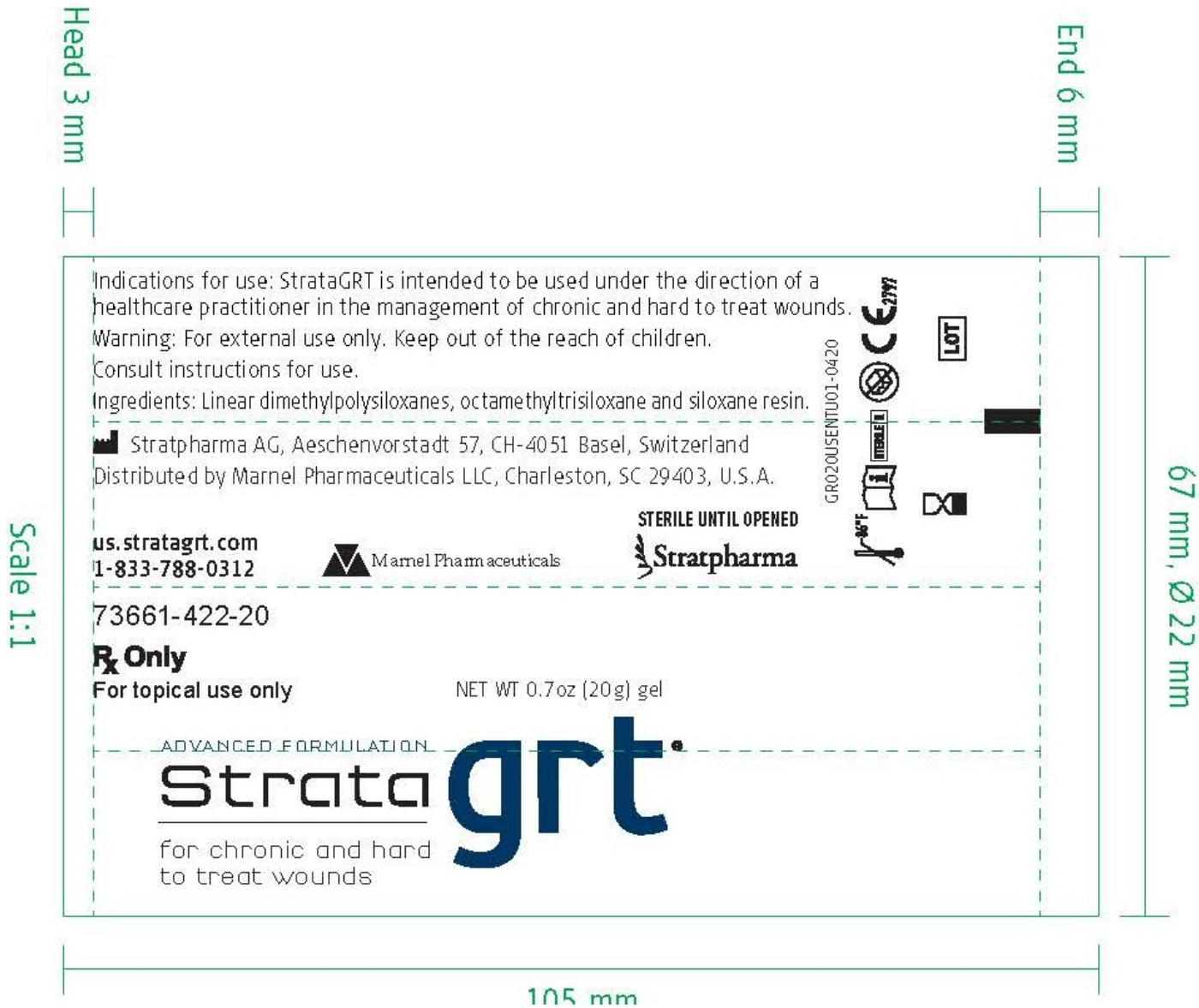
LOT

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

gel
0.7oz
20g

℞ Only
For topical use only

73661-422-20



STRATAGRT

dressing, wound, occlusive

Product Information			
Product Type	MEDICAL DEVICE	**Item Code (Source)**	NHRIC:73661-422

Inactive Ingredients	
Ingredient Name	**Strength**
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRISILOXANE (UNII: 9G1ZW13R0G)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:73661-422-20	1 in 1 BOX		

1		20 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
exempt device	NAD	07/07/2020	

Labeler - Marnel Pharmaceuticals, Inc. (080161449)

Establishment

Name	Address	ID/FEI	Business Operations
Stratpharma AG		483232695	manufacture

Revised: 7/2020 Marnel Pharmaceuticals, Inc.