# **DERMELLE-** dressing, wound, occlusive **Scite Pharma**, **LLC**

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ADVANCED FORMULATION Dermelle scar therapy gel

# **Rx Only**

For topical use only

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

# **Description**

# Dermelle is a transparent gel formulation for the management of scars, both old and new.

When used as directed Dermelle 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.

Dermelle 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.

#### Indication for use

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

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

- general and cosmetic surgery
- trauma
- chronic wounds
- burns
- bites
- acne, and other diseases of the skin.

Dermelle is indicated to soften and flatten scars, relieve the itching and discomfort as well as to reduce redness and discoloration associated with scars.

Dermelle is used for the topical management of keloids and hypertrophic scars.

It contains no alcohols, parabens or fragrances.

Dermelle is suitable for children or people with sensitive skin.

Dermelle is suitable to use on infants, during pregnancy and whilst breastfeeding.

Dermelle is intended for single patient use.



On the first use of 1 oz (28.5 g) tubes remove the cap, then the protective seal and close with the cap after use.

#### **Directions for use**

Ensure that the scar is clean and dry.

Apply a very thin layer of Dermelle to the scar and allow to dry.

When applied correctly, Dermelle should be dry in 3-4 minutes.

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.

Once dry, Dermelle can be covered with sunscreen, cosmetics, pressure garments or casts.

Dermelle should be applied once daily, or twice daily to exposed areas or as advised by your physician.

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

#### How much Dermelle do I need?

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

**Dermelle 1 oz (28.5 g)** is enough to treat an area of  $5 \times 5$  inch (12  $\times$  12 cm) twice per day for 30 days.

# **Warning**

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

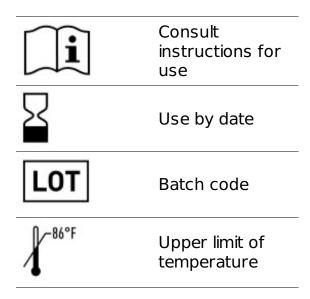
Do not administer to patients with known hypersensitivity to the ingredients of this product.

Ingredients: Polydimethylsiloxane, hydroxylsiloxane and alkyl siloxane resin.

# How supplied

Dermelle 1 oz (28.5 g) tube

**Product identification code:** 79043-110-28



Stratpharma AG Aeschenvorstadt 57 CH-4051 Basel Switzerland

Distributed by Allegis Pharmaceuticals Canton, MS 39046, USA

Date of preparation of this information: 09/2020

Stratpharma Switzerland

scite PHARMA

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# PRINCIPAL DISPLAY PANEL - 28.5 g Tube Box

79043-110-28

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gel 1 oz 28.5 g

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Dermelle scar therapy gel



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#### **Product Information**

Inactive Ingredients				
Ingredient Name	Strength			
DIMETHICONE (UNII: 92RU3N3Y1O)				
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)				
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NHRIC:79043-110- 28	1 in 1 BOX				
1		28.5 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	MDA	12/15/2020	12/01/2025			

# Labeler - Scite Pharma, LLC (117555106)

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