

DERMELLE- dressing, wound, occlusive
Scite Pharma, LLC

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 × 5 inch (12 × 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

	Consult instructions for use
	Use by date
	Batch code
	Upper limit of temperature

Stratpharma AG
Aeschenvorstadt 57
CH-4051 Basel
Switzerland

Distributed by
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Canton, MS 39046, USA

Date of preparation of this
information: 09/2020

Stratpharma
Switzerland

scite
PHARMA

Questions:
1-866-633-9033

CE

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PRINCIPAL DISPLAY PANEL - 28.5 g Tube Box

79043-110-28

Rx Only
For topical use only

gel
1 oz
28.5 g

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scar therapy gel



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Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:79043-110
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Inactive Ingredients

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

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)

Revised: 7/2023

Scite Pharma, LLC