

**STRATATRIZ- dressing, wound, occlusive**  
**Marnel Pharmaceuticals, Inc.**

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**StrataTriz**

**Rx Only**

For topical use only

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

**[EN] Description**

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

When used as directed StrataTriz 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.

StrataTriz 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**

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

StrataTriz 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.

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

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

It contains no alcohols, parabens or fragrances.

StrataTriz is suitable for children or people with sensitive skin.

StrataTriz is suitable to use on infants, during pregnancy and whilst breast-feeding.

StrataTriz is intended for single patient use.

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

**Directions for use**

Ensure that the scar is clean and dry.

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

When applied correctly, StrataTriz 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, StrataTriz can be covered with sunscreen, cosmetics, pressure garments or casts.

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

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

### **How much StrataTriz do I need?**

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

**StrataTriz 0.7 oz (20g)** is enough to treat an area of 5x5 inch (12x12cm) twice per day for 30 days.

### **Warning**

- For external use only.
- StrataTriz should not be applied on third degree burns or to open wounds.
- StrataTriz should not be placed in contact with mucous membranes or the eyes.
- StrataTriz should not be applied over topical medications unless advised by your physician.
- StrataTriz 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, hydroxysiloxane and alkyl siloxane resin.

### **How supplied:**

StrataTriz 0.7 oz (20g) tube

### **Product identification code:**

73661-424-20

Head 3 mm

End 6 mm

Indications for use: StrataTriz is intended to be used under the direction of healthcare practitioners in the management of scars.

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

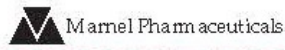
Consult instructions for use.

Ingredients: Polydimethylsiloxane, hydroxylsiloxane and alkyl siloxane resin.

Stratpharma AG, Aeschenvorstadt 57, CH-4051 Basel, Switzerland

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



STO20USENTU01-0420



LOT



73661-424-20

**Rx Only**

For topical use only

NET WT 0.7oz (20g) gel

ADVANCED FORMULATION

Strata **triz**<sup>®</sup>

scar therapy gel

67 mm, Ø 22 mm

Scale 1:1

105 mm



## STRATATRIZ

dressing, wound, occlusive

### Product Information

<b>Product Type</b>	MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:73661-424
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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:73661-424-20	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
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exempt device	NAD	07/15/2020	
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**Labeler** - Marnel Pharmaceuticals, Inc. (080161449)

**Establishment**

Name	Address	ID/FEI	Business Operations
Stratpharma AG		483232695	manufacture

Revised: 7/2020

Marnel Pharmaceuticals, Inc.