

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

-----  
**StrataMark**

**R<sub>x</sub> Only**

**For topical use only**

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

**[EN]Description**

StrataMark is a rapidly drying, non-sticky, transparent gel formulation for the management of Striae Distensae (stretch marks).

When used as directed, StrataMark dries to form a thin, flexible and protective layer, that is gas permeable and water-proof which hydrates and protects stretch marks, allowing the skin to normalize the collagen synthesis cycle.

StrataMark is suitable for all areas of the skin, including exposed and sensitive areas, as well as large areas of the body (i.e. buttocks, abdomen, thighs, breasts and back).

**Indication for use**

StrataMark is intended to be used under the direction of healthcare practitioners in the management of stretch marks.

StrataMark is indicated for the management of all types of stretch marks, particularly those covering a wide surface area, resulting from pregnancy, adolescent growth spurts, weight gain or loss, or bodybuilding.

StrataMark is indicated to soften and flatten stretch marks, reduce redness and discoloration associated with stretch marks as well as to relieve the itching and discomfort of stretch marks.

It contains no alcohols, parabens or fragrances.

StrataMark is suitable for pregnant women, breastfeeding mothers, children and people with sensitive skin.

StrataMark is intended for single patient use.

**Directions for use**

**On the first use of 1.75 oz (50g) tubes, remove the cap, then the protective seal and close with the cap after use.**

Ensure that the skin is clean and dry.

Apply a very thin layer of StrataMark to the relevant areas with the fingertips and distribute evenly to form a very thin layer and allow the gel to dry.

When applied, StrataMark 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.

Once dry, StrataMark can be covered with undergarments, sunscreens or cosmetics.

StrataMark should be applied once per day or as advised by your physician.

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

**How much StrataMark do I need?**

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

**StrataMark 1.75 oz (50g)** is enough to treat an area of 12x12 inch (30x30cm) for 30 days.

**Warning**

- For external use only.
- StrataMark should not be applied to third degree burns or to open wounds.
- StrataMark should not be placed in contact with eyes.
- StrataMark should not be applied over other skin treatments without the advice of your physician.
- StrataMark 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:** Dimethylpolysiloxane, dihydroxysiloxane and alkylmethylsiloxane.

**How supplied:**

StrataMark 1.75 oz (50g) tube

**Product identification code:**

73661-423-50

135 mm

www.us.stratamark.net

Indications for use: StrataMark is intended to be used under the direction of a healthcare practitioner in the management of stretch marks.  
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: Dimethylpolysiloxane, dihydroxysiloxane and alkylmethylsiloxane.  
See package insert for full information.

SK050USENBK02-0420

35.5 mm

73661-423-50

**Rx Only**  
For topical use only

ADVANCED FORMULATION

**Strata mark**<sup>®</sup>

gel  
1.75oz  
50g

for the management  
of stretch marks

gel  
1.75oz  
50g

www.us.stratamark.net



73661-423-50



Stratapharma AG, Aeschenvorstadt 57, CH-4051 Basel, Switzerland  
Distributed by Marnel Pharmaceuticals LLC,  
Charleston, SC 29403, U.S.A.

us.stratamark.net 1-833-788-0312



40 x 16 mm

www.us.stratamark.net

73661-423-50



**Strata mark**<sup>®</sup>  
ADVANCED FORMULATION  
for the management  
of stretch marks

73661-423-50  
**Rx Only**  
For topical use only  
gel  
1.75oz  
50g



## STRATAMARK

dressing, wound, occlusive

### Product Information

<b>Product Type</b>	MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:73661-423
---------------------	----------------	---------------------------	-----------------

### Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6 Y)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:73661-423-50	1 in 1 BOX		
1		50 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	07/11/2020	

**Labeler** - Marnel Pharmaceuticals, Inc. (080161449)

## Establishment

Name	Address	ID/FEI	Business Operations
Stratpharma AG		483232695	manufacture

Revised: 7/2020

Marnel Pharmaceuticals, Inc.