

SILIPAC- elastomer, silicone, for scar management
SILIGEL- elastomer, silicone, for scar management
Sterling-Knight Pharmaceuticals, LLC

Silipac Kit

Silipac Kit

Rx Only (Prescription Only)

DESCRIPTION:

For Old and New Scars

- Reduces redness
- Softens and flattens raised scars
- Relieves itching, discomfort and pain associated with scars
- Helps prevent excessive and abnormal scar formation
- For use as mono-therapy or in combination with other scar therapies, including pressure garments.

Ingredients:

Gel contains: Dimethicone, Dimethicone Crosspolymer, Trimethylsiloxysilicate.

Gel Pad contains: Silicone (as Polysiloxane in a gel base).

CLINICAL PHARMACOLOGY:

The exact mechanism of silicone gel patches in improving the appearance of scar tissue remains unknown. However, numerous mechanisms have been suggested to explain the efficacy of silicone gel patch, including hydration, pressure, temperature, oxygen transmission and silicone absorption. There is some evidence that the treatment affects the stratum corneum and, by reducing evaporation, restores better homeostasis in the tissue. In keloid and hypertrophic scarring, the stratum corneum allows more evaporation of water from the underlying tissue than occurs in normal skin. Silicone patches may prevent this, keeping the stratum corneum in optimal hydration and protecting the skin from environmental hazards, both of which can reduce abnormal scarring. The silicone gel patch may also affect the stratum corneum by inhibiting mast cell activity, diminishing edema, vasodilatation and excessive extracellular matrix formation but the simple changes in temperature, pressure, oxygen tension and hydration produced by wound coverage probably constitute the main mechanism of action. Another hypothesis is that the effect of static electricity on silicone may influence the alignment of collagen deposition.

INDICATIONS AND USES:

For external use only. Silipac is intended for non-invasive management of old and new scars, including hypertrophic and keloid scars resulting from burns, surgical procedures and trauma. It is effective for the management of both existing and new hypertrophic or keloid scars and as a prophylactic treatment on closed wounds.

CONTRAINDICATIONS:

Silipac is contraindicated in patients with known hypersensitivity to silicone or any of the listed ingredients.

WARNINGS:

For external use. Do not apply to an open wound or third degree burn. Never use on a sutured wound until sutures have been removed. In rare instances, silicone patch may cause a rash on the skin. This condition may result from improper cleansing of the scar area where the silicone patch has been applied. If this product is applied properly and skin irritation still occurs, discontinue use and consult your physician.

PRECAUTIONS:

Stop use and ask a doctor if irritation develops. In rare instances, silicone sheets may cause a rash on the skin. This condition may result from improper cleansing of the scar area where the silicone patch has been applied. If this product is applied properly and skin irritation still occurs, discontinue use and consult your physician. If ingested, get medical help or contact Poison Control Center right away. **KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.**

Call your doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088. **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

Caution:

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

ADVERSE REACTIONS:

Silipac may cause transient redness stinging, burning or irritation, however, it normally disappears when discontinuing the use of the patches.

DOSAGE AND ADMINISTRATION:

1. Wash your hands and the scar area with soap and water. Dry thoroughly.
2. When not wearing pad, apply gel onto affected area. Ensure that the affected area is clean and dry. Apply Gel to the area as a very thin coat and allow to dry. Apply gel twice daily. Once dry, gel can be covered with cosmetics or sunscreen.
3. Cut the patch to fit the scar area so that the edges of the gel patch extend at least 1/4" beyond the scar on all sides.
4. Peel of the strip and place the sticky side of the patch directly onto the scar or wound. Leave on for 8-12 hours per day then remove. Do not discard the mylar release strip.
5. Discard the patch and replace with a new patch every 5 - 7 days.
6. When not wearing the patch, place the patch back onto the mylar release strip.

HOW SUPPLIED:

Each carton of Silipac contains the following:

1 x 30ml Gel NDC 69336-806-30

4 x Gel Pads packed in individually (5cmx14cm) NDC 69336-805-01

2 x Gel Pads packed in individually (5cmx14cm) NDC 69336-805-02

STORAGE:

Store at controlled room temperature 15°-30°C (59°F-86°F). Keep in cool dry place. Protect from light and moisture.



Distributed By:
Sterling-Knight Pharmaceuticals, LLC
Ripley, MS 38663
Rev 0818-1
Product Code: 805



Rx Only

NDC 69336-806-30

Siligel

30g

Ingredients: Dimethicone, Dimethicone Crosspolymer, Trimethylsiloxysilicate.

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

DIRECTIONS: Ensure that the affected area is clean and dry. Apply Siligel to the area as a very thin coat and allow to dry. Apply Siligel twice daily. Once dry, Siligel can be covered with cosmetics or sunscreen. Recommended duration of treatment 60-90 days.

WARNING: Avoid direct contact with eyes, mucous membranes, third degree burns and open wounds. Siligel should not be used on dermatological conditions that disrupt the integrity of the skin. For external use only. If irritation occurs, discontinue use and consult your physician. Keep this product out of the reach of children. Store below 25°C/77°F.

INDICATION FOR USE: Siligel is intended for the management of old and new scars, including hypertrophic and keloid scars, resulting from general surgical procedures, trauma, wounds and burns.

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Sterling-Knight Pharmaceuticals, LLC
Ripley, MS 38663



Made in USA
Item 306
Rev 0818-01

Distributed By:

Sterling-Knight Pharmaceuticals, LLC
Ripley, MS 38663
Rev 0818-1
Product Code: 806

SILIPAC

elastomer, silicone, for scar management

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:69336-805
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69336-805-01	4 in 1 CARTON		
1		1 in 1 POUCH; Type 1: Convenience Kit of Co-Package		
2	NHRIC:69336-805-02	2 in 1 CARTON		
2		1 in 1 POUCH; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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premarket notification	K083718	08/07/2018	
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SILIGEL

elastomer, silicone, for scar management

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:69336-806
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69336-806-30	1 in 1 CARTON		
1		1 in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K083718	08/07/2018	

Labeler - Sterling-Knight Pharmaceuticals, LLC (079556942)

Establishment

Name	Address	ID/FEI	Business Operations
Sterling-Knight Pharmaceuticals, LLC		079556942	manufacture

Revised: 8/2018

Sterling-Knight Pharmaceuticals, LLC