

SILHEAL-10 GEL-PAD KIT- elastomer, silicone, for scar management

Forreal Pharmaceuticals LLC

SilHeal-10

USES:

Intended for managing hypertrophic, hyperpigmented and keloid scar tissue.

HOW SUPPLIED:

Non-sterile product is labeled as such and supplied in protective packaging and container.

POSSIBLE REACTIONS

INCLUDE:

- Superficial maceration of the skin
- Pruritus
- Skin discoloration
- Rash

Rashes may occur on skin under gel-pad due to poor hygiene. Rashes may also result from wrapping gel-pad too tightly around skin. Stop use and ask a doctor if gel-pad is applied properly and skin irritation still occurs.

Discoloration of skin covered by gel-pad may temporarily occur in patients with darker complexions.

Do not use creams, lotions, sun block, or other silicone products on your skin when wearing gel-pad. Only apply gel-pad to clean, bare skin.

PRECAUTIONS:

Do not apply to open wounds or third degree burns. Never use on a sutured wound until sutures have been removed or when any dermatological conditions disrupt the skin (such as a rash or burn). 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 gel-pad has been applied. Stop use and ask a doctor if product is applied properly and skin irritation still occurs. Persons with dermatological disorders should contact their doctor prior to using this product.

DIRECTIONS FOR USE:

- 1) Wash your hands and the scar area with soap and water. Dry thoroughly.
- 2) Cut the gel-pad to fit the scar area as needed, so that the edges extend at least 1/4" beyond the scar on all sides.
- 3) Gently peel the gel-pad from the mylar release strip (it is normal for small bits of the gel to remain on the mylar release strip). Do not discard the mylar release strip.
- 4) Place the sticky side of the gel-pad directly onto the scar. For best results, wear the gel-pad 8-12 hours per treatment. Wait 8-12 hours without use before next treatment.

5) When not wearing the gel-pad, place the gel-pad (sticky side) back onto the mylar release strip. Place the gel-pad back into the original pouch for protection.

7) When the sticky side of the gel-pad appears dirty or worn, use your finger to gently wash the gel-pad with soap and water, as needed. Rinse with water and allow to air dry. The stickiness will return once dry. Do not fold while washing or drying.

* Proper use, and gentle care of the gel-pad will be re-usable up to eight (8) days.

Repackaged For:
ForReal, Pharmaceuticals, LLC
Royal Oak, MI 48067

Product Label

NDC **81877-511-10**

SilHeal-10

Scar Treatment

MEDICAL GRADE SILICONE MATRIX

TEN (10) GEL-PADS

3" X 5.5" (NON-STERILE)

ForReal, Pharmaceuticals, LLC

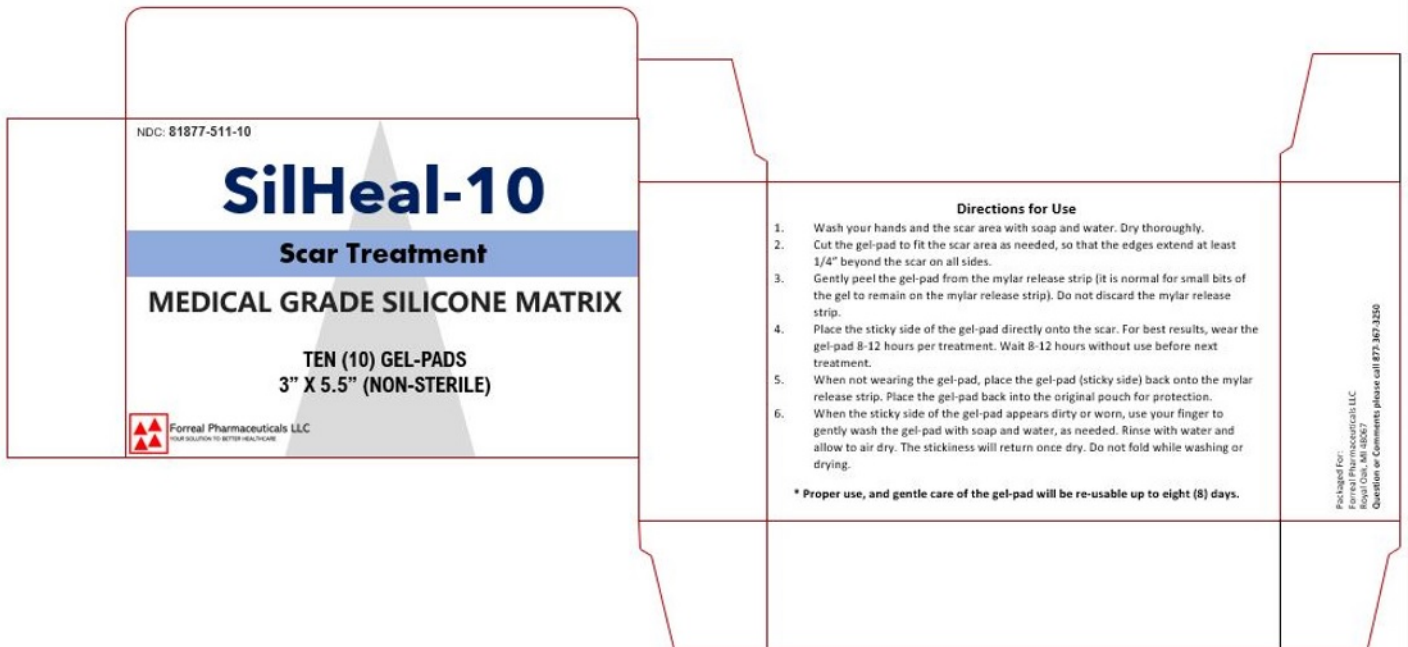
Your solution to better healthcare.

Directions for Use

1. Wash your hands and the scar area with soap and water. Dry thoroughly.
2. Cut the gel-pad to fit the scar area as needed, so that the edges extend at least 1/4" beyond the scar on all sides.
3. Gently peel the gel-pad from the mylar release strip (it is normal for small bits of the gel to remain on the mylar release strip). Do not discard the mylar release strip.
4. Place the sticky side of the gel-pad directly onto the scar. For best results, wear the gel-pad 8-12 hours per treatment. Wait 8-12 hours without use before next treatment.
5. When not wearing the gel-pad, place the gel-pad (sticky side) back onto the mylar release strip. Place the gel-pad back into the original pouch for protection.
6. When the sticky side of the gel-pad appears dirty or worn, use your finger to gently wash the gel-pad with soap and water, as needed. Rinse with water and allow to air dry. The stickiness will return once dry. Do not fold while washing or drying.

*** Proper use, and gentle care of the gel-pad will be re-usable up to eight (8) days.**

Packaged For:
 ForReal Pharmaceuticals, LLC
 Royal Oak, MI 48067
Question or Comments please call 877-367-3250



Inner Foil



Insert

USES:

Intended for managing hypertrophic, hyperpigmented and keloid scar tissue.

HOW SUPPLIED:

Non-sterile product is labeled as such and supplied in protective packaging and container.

POSSIBLE REACTIONS INCLUDE:

- Superficial maceration of the skin
- Skin discoloration
- Pruritus
- Rash

Rashes may occur on skin under gel-pad due to poor hygiene. Rashes may also result from wrapping gel-pad too tightly around skin. Stop use and ask a doctor if gel-pad is applied properly and skin irritation still occurs.

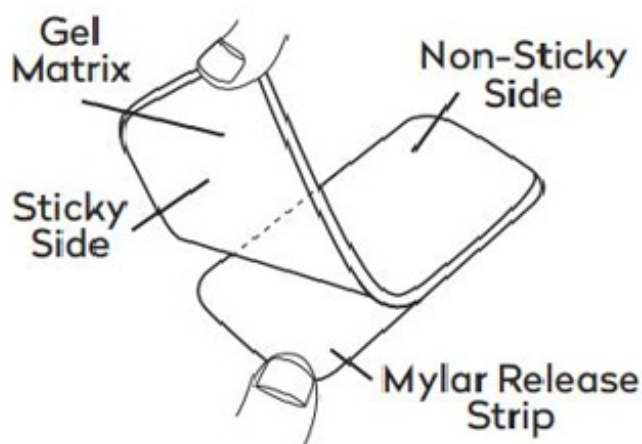
Discoloration of skin covered by gel-pad may temporarily occur in patients with darker complexions.

Do not use creams, lotions, sun block, or other silicone products on your skin when wearing gel-pad. Only apply gel-pad to clean, bare skin.

PRECAUTIONS:

Do not apply to open wounds or third degree burns. Never use on a sutured wound until sutures have been removed or when any dermatological conditions disrupt the skin (such as a rash or burn). 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 gel-pad has been applied. Stop use and ask a doctor if product is applied properly and skin irritation still occurs. Persons with dermatological disorders should contact their doctor prior to using this product.

DIRECTIONS FOR USE:



1) Wash your hands and the scar area with soap and water. Dry thoroughly.

2) Cut the gel-pad to fit the scar area as needed, so that the edges extend at least 1/4" beyond the scar on all sides.

3) Gently peel the gel-pad from the mylar release strip (it is normal for small bits of the gel to remain on the mylar release strip). Do not discard the mylar release strip.

4) Place the sticky side of the gel-pad directly onto the scar. For best results, wear the gel-pad 8-12 hours per treatment. Wait 8-12 hours without use before next treatment.

5) When not wearing the gel-pad, place the gel-pad (sticky side) back onto the mylar release strip. Place the gel-pad back into the original pouch for protection.

7) When the sticky side of the gel-pad appears dirty or worn, use your finger to gently wash the gel-pad with soap and water, as needed. Rinse with water and allow to air dry. The stickiness will return once dry. Do not fold while washing or drying.

* Proper use, and gentle care of the gel-pad will be re-usable up to eight (8) days.

SILHEAL-10 GEL-PAD KIT

elastomer, silicone, for scar management

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRC:81877-511
---------------------	----------------	---------------------------	----------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRC:81877-511-10	10 in 1 BOX		
1		1 in 1 POUCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K001608	11/01/2021	

Labeler - Forreal Pharmaceuticals LLC (118029197)