

**CICASIL SILICONE GEL-PAD- elastomer, silicone, for scar management
Blaine Labs Inc.**

CICASIL™ SILICONE GEL-PAD

PRESCRIPTION ONLY

USES:

CICASIL™ SILICONE GEL-PAD is 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.
- 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.

Product Package

PRESCRIPTION ONLY

BLAINE LABS

NDC 63347- 170-01

MDA-K001608

US PATENT # 6,572,878

CICASILTM

S I L I C O N E G E L - P A D

MEDICAL-GRADE SILICONE GEL MATRIX
FOUR (4) GEL-PADS - 2" x 5.5" (NON-STERILE)

RX ONLY

BLAINE LABS

CICASILTM

S I L I C O N E G E L - P A D

RX ONLY

**MADE FROM THE FINEST MEDICAL-GRADE SILICONE MATRIX
EASY-TO-USE, COMFORTABLE TO WEAR
WASHABLE AND REUSABLE**

CICASILTM SILICONE GEL-PAD IS ABLE TO BE CUT AS NEEDED

QUESTIONS OR COMMENTS? 800.307.8818 M-F, 8:00 AM-5:00 PM (PST)

MANUFACTURED BY:

BLAINE LABS, INC.

1 1 0 3 7 LOCKPORT PLACE

SANTA FE SPRINGS, CA 90670

BLAINELABS.COM

PLEASE RECYCLE! THIS
PACKAGE IS MADE FROM
RECYCLABLE MATERIALS.

04200-01-P-BOX

REV20191121

LOT NO

03/20/2021

MADE IN THE USA
WARRANTY
WARRANTY

BLAINE LABS INC.
1100 CROWN BLVD
MOUNTAIN VIEW, CO 80501

03/20/2021

MADE FROM THE FINEST MEDICAL-GRADE SILICONEMATRIX
EASY-TO-USE, COMFORTABLE TO WEAR
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CICASIL™ SILICONE GEL-PAD IS ABLE TO BE CUT AS NEEDED

RX ONLY

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SILICONE GEL-PAD



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CICASIL™
SILICONE GEL-PAD

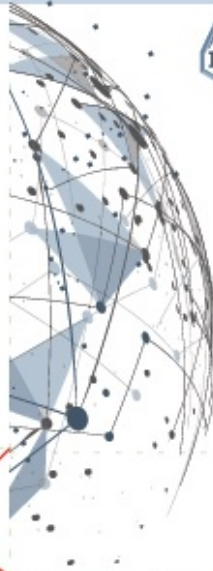
MEDICAL-GRADE SILICONE GEL MATRIX

FOUR (4) GEL-PADS - 2" x 5.5" (NON-STERILE)

RX ONLY

LOT NO.

0 60100 82791 9



Zipper

DURABLE • REUSABLE • WASHABLE

RX ONLY

DURABLE • REUSABLE • WASHABLE

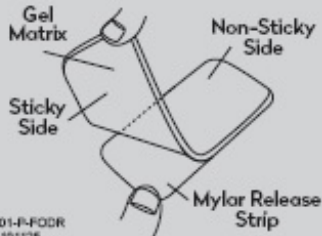


NDC 63347-170-01
MDA-K001608
US PATENT # 6,572,878

CICASIL™

SILICONE GEL-PAD

A safe and effective method for managing hypertrophic, hyperpigmented and keloid scar tissue.



04200-01-F-PDDR
REV20191125

Directions

- 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.
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- 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.

The gel-pad is effective as long as it retains its stickiness. After several applications, the gel-pad may appear worn out, but if it sticks to the skin it will keep working. Proper use, and gentle care of the gel-pad will be re-usable up to eight (8) days.

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 cleaning 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.

Sealed side area 0.25" (qty4)

FRONT

OPENING

BOTTOM

UNPRINTED

CICASIL™

SILICONE GEL-PAD

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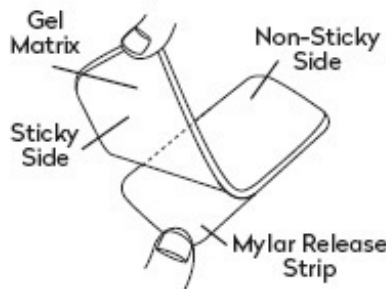
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REV20191126

04200-01-IN501

res

CICASIL SILICONE GEL-PAD
elastomer, silicone, for scar management

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:63347-170
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:63347-170-01	4 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K001608	09/14/2017	

Labeler - Blaine Labs Inc. (017314571)**Establishment**

Name	Address	ID/FEI	Business Operations
Blaine Labs Inc.		017314571	manufacture

Revised: 1/2020

Blaine Labs Inc.