

**VISILAGE RX SILICONE GEL-PAD- elastomer, silicone, for scar management
Vivera Pharmaceuticals, Inc.**

VISILAGE R_X SILICONE GEL-PAD

**VISILAGE R_X[®]
SILICONE GEL-PAD**

BY PRESCRIPTION ONLY

USES:

Visilage RX Silicone Gel-Pad[®] is intended for use in management and prevention of hypertrophic, keloid, and hyperpigmented scars from burns, surgeries, or traumatic injury of the skin.

CONTRAINDICATIONS:

Do not use on open wounds, sutured wounds, or when any dermatological conditions disrupt the skin (such as a rash or burn).

HOW SUPPLIED:

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

WARNINGS, PRECAUTIONS, ADVERSE REACTIONS:

Possible complications include:

- Superficial maceration of the skin
- Skin discoloration
- Sheeting tack and thickness vary
- Rash
- Pruritus (itching skin)

Rashes may occur on skin under gel sheet due to poor or insufficient hygiene. Rashes may also result from wrapping gel sheet too tightly around skin. Should a rash or irritation of skin occur, stop use for a minimum 12 hours or until irritation subsides. If rash persists, discontinue use and contact a physician.

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

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

In case of consumption seek professional assistance or contact a Poison Control Center immediately at 1-800-222-1222.

DIRECTIONS FOR USE:

- 1) Wash your hands and the scar area with soap and water. Dry thoroughly.
- 2) Measure the **Visilage Rx Silicone Gel-Pad[®]** to fit the scar area so that the edges of the gel-pad extend at least 1/4" beyond the scar on all sides. Cut as needed.
- 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 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 fingers to gently wash the gel-pad with anti-bacterial 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.

* Gel-Pad will last eight (8) days with proper use and gentle care.

PRECAUTIONS:

Do not apply to an open wound or second/third degree burns. Never use on a sutured wound until sutures have been removed. 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 pad has been applied. If this product is applied properly and skin irritation still occurs, discontinue use and consult your physician. Persons with dermatological disorders should contact their physician prior to using this product.

Principal Display Panel

**VIVERA®
PHARMACEUTICALS**

**VISILAGE Rx®
SILICONE GEL-PAD**

BY PRESCRIPTION ONLY

**VIVERA® □
PHARMACEUTICALS**

NDC# 72380-101-10

**VISILAGE Rx®
SILICONE GEL-PAD**

LOT NO.:

EXPIRATION:

MEDICAL-GRADE SILICONE GEL MATRIX

US PATENT # 6,572,878

15 DAY SUPPLY - TWO (2) GEL-PADS - 2" x 5.5" (NON-STERILE)

6 16728 00067 5

□ DIRECTIONS FOR USE:

- 1) Wash your hands and the scar area with soap and water. Dry thoroughly.
- 2) Measure the Visilage Rx Silicone Gel-Pad® to fit the scar area so that the edges of the gel-pad extend at least 1/4" beyond the scar on all sides. Cut as needed.
- 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 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 fingers to gently wash the gel-pad with anti-bacterial 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.

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PRECAUTIONS:

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 sheets may cause a rash on the skin. This condition may result from improper cleansing of the scar area where the silicone pad has been applied. If this product is applied properly and skin irritation still occurs, discontinue use and consult your physician. Persons with dermatological disorders should contact their physician prior to using this product.

**KEEP OUT OF THE REACH OF CHILDREN.
FOR EXTERNAL USE ONLY.**

STORE AT 20°-25°C (68° TO 77°F); KEEP AWAY FROM HEAT AND PROTECT FROM FREEZING.

**VIVERA®
PHARMACEUTICALS**

MANUFACTURED FOR:
VIVERA PHARMACEUTICALS, INC.
4533 MACARTHUR BLVD. #5049
NEWPORT BEACH, CA 92660

MADE IN USA

THIS PACKAGE IS MADE FROM
RECYCLABLE MATERIALS.

US PATENT # 6,572,878
04000-03-P-BOX
REV20190114

Zipper

DURABLE • REUSABLE • WASHABLE

RESEALABLE PACKAGE!

DURABLE • REUSABLE • WASHABLE

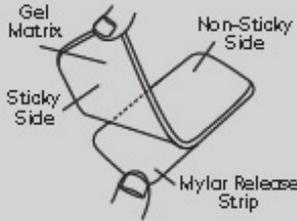


NDC# 72340-101-10
USPATENT # 6,572,873

VISILAGER[®]

SILICONE GEL-PAD

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



MANUFACTURED FOR: VIVERA PHARMACEUTICALS, LLC
4122 MACARTHUR BLVD. #1049 • DUNFORTH ESTATES, CA 92620
04-000-02-F-POIL REV20100114

DIRECTIONS FOR USE

- 1) Wash your hands and the scar area with soap and water. Dry thoroughly.
- 2) Cut the Visilager[®] Silicone Gel-Pad to fit the scar as needed so that the edges of the gel-pad extend at least 1/4" beyond the scar on all sides.
- 3) Gently peel the gel-pad from the mylar release strip (do so no further than 1/2" of the gel-pad from the mylar release strip). Do not touch the mylar release strip.
- 4) Place the sticky side of the gel-pad directly onto the scar. For best results, wear the pad 2-12 hours per treatment. Wear 2-12 hours while it is in the next treatment.
- 5) When re-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 fingers to gently wash the gel-pad with a pH-balanced soap and water, as needed. Place with water and allow to air dry. The stickiness will return once dry. Do not fold while washing or drying.

* Gel-Pad will last eight (8) days with proper use and gentle care.

PRECAUTIONS

Do not apply to an open wound or third degree burn. How rare or a standard wound or burn may have been treated, it is best to consult your doctor. Do not use on this site. This condition may occur from any procedure using of the scar area while the silicone pad has been applied. If this product is applied to a patient with a skin condition, discontinue use and consult your physician. As used with dermatological diseases to skin consult their physician prior to using this product.

STORAGE: 20°-24°C (68°F TO 77°F); KEEP AWAY FROM HEAT AND PROTECT FROM FREEZING.

LOT NO:
EXPIRATION:

Sealed side area 0.25" (qty:4)

UNPRINTED

LOT# EXP DATE STAMPED

↓ Patient Insert ↓



VISILAGE[®]

SILICONE GEL-PAD

NDC# 72380-101-10
US PATENT # 6,572,878

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Possible complications include:

- Superficial maceration of the skin
- Sheeting tack and thickness vary
- Pruritus (itching skin)
- Skin discoloration
- Rash

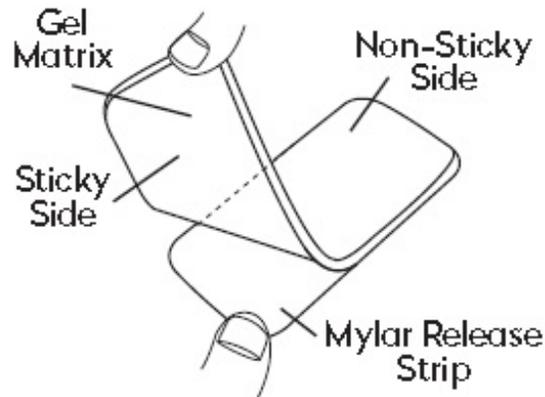
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MANUFACTURED FOR:

VIVERA PHARMACEUTICALS, INC.
4533 MACARTHUR BLVD. #5049
NEWPORT BEACH, CA 92660 1-844-4VIVERA

STORE AT 20°-25°C (68° TO 77°F); KEEP AWAY FROM HEAT AND PROTECT FROM FREEZING.

VIV-IN-04 REV20190114

VISILAGE RX SILICONE GEL-PAD

elastomer, silicone, for scar management

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:72380-101
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:72380-101-10	2 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	12/01/2018	

Labeler - Vivera Pharmaceuticals, Inc. (081244342)**Registrant** - Vivera Pharmaceuticals, Inc. (081244342)