

SILTREX SILICONE GEL-PAD- elastomer, silicone, for scar management
Viverra Pharmaceuticals, Inc.

SILTREX® SILICONE GEL-PAD

SILTREX®
SILICONE GEL-PAD

BY PRESCRIPTION ONLY

USES:

Siltrex Silicone Gel-Pad® is intended for use in the management, control, and prevention of old and new hypertrophic or keloid scars resulting from burns or surgical or traumatic injury of the skin.

HOW SUPPLIED:

Non-sterile product is labeled as such and supplied in a protective package within a protective outer container.

CONTRAINDICATIONS:

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

WARNINGS, PRECAUTIONS, ADVERSE REACTIONS:

Possible complications include:

- Superficial maceration of the skin • Skin discoloration
- Sheeting tack and thickness vary • Rash
- Pruritus

Rashes have been observed on skin under the gel sheeting, this has been attributed to poor or insufficient hygiene. Similar rashes have been attributed to gel sheeting being wrapped too tightly. Should a rash or irritation of the skin occur, stop use of the gel sheeting for at least 12 hours or until the rash or irritation completely subsides. If the rash persists, a physician should be contacted, and gel sheeting use should be discontinued.

Discoloration of the skin covered by silicone gel sheeting has been reported, particularly in dark skinned patients. This effect appears to be transient and may be similar to the discoloration experienced whenever an area of skin is covered for extended periods of time.

Perception of tack is subjective, and the adhesive characteristic of the **Siltrex Silicone Gel-Pad®** may vary. These variations do not affect the function of the product.

Small bubbles may form after repeated use and washing. This does not have an impact on the function of the product.

Do not use creams, lotions, sun block or other silicone products on your skin when wearing silicone gel sheeting. These products will create a barrier between the scar site and silicone gel preventing a proper healing environment.

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

DIRECTIONS FOR USE:

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

- 2) Measure the Siltrex 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 finger 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 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 conditions should contact their physician prior to using this product.

Principal Display Panel

**VIVERA®
PHARMACEUTICALS**

**SILTREX®
SILICONE GEL-PAD**

BY PRESCRIPTION ONLY

**VIVERA® NDC# 72380-183-03
PHARMACEUTICALS**

**SILTREX®
SILICONE GEL-PAD**

BY PRESCRIPTION ONLY

LOT NO.

SEE INDIVIDUAL COMPONENTS FOR EXP DATE

MEDICAL-GRADE SILICONE GEL MATRIX
(PATENTED TECHNOLOGY & FORMULA)
15 DAY SUPPLY - TWO (2) GEL-PADS - 2” x 5.5” (NON-STERILE)

DIRECTIONS FOR USE:

- 1) Wash your hands and the scar area with soap and water. Dry thoroughly.
- 2) Measure the **SILTREX 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 finger 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 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
11100 GREENSTONE AVE.
SANTA FE SPRINGS, CA 90670

MADE IN USA

THIS PACKAGE IS MADE FROM RECYCLABLE MATERIALS.

04000-02-P-BOX
REV20180925

MEDICAL-GRADE SILICONE GEL MATRIX
(PATENTED TECHNOLOGY & FORMULA)
15 DAY SUPPLY - TWO (2) GEL-PADS - ZIPPER® (NON-STERILE)

SILTREX® SILICONE GEL-PAD



LOT NO
SILICONE GEL-PAD COMPONENTS FOR DATE

NDC # 72391-183-03

BY PRESCRIPTION ONLY

SILTREX® SILICONE GEL-PAD



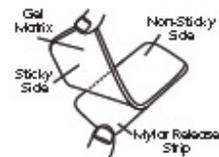
DIRECTIONS FOR USE:

- 1) Wash your hands and the sore area with soap and water thoroughly.
- 2) Moisten the SILTREX Silicone Gel-Pad to fit the sore area, so that the edge of the gel pad conforms to the shape of the sore or abrasion. Do not stretch.
- 3) Gently peel the gel pad from the mylar release strip. Do so without the mylar release strip.
- 4) Place the sticky side of the gel pad directly to the sore. For best results, wash the sore with soap and water to remove any debris before application.
- 5) When sores heal, the gel pad will peel off. Do not pull it off. The gel pad will peel off naturally.
- 6) Wash the sticky side of the gel pad and apply a different mylar release strip to get the gel pad ready to use. Wash the sticky side of the gel pad with soap and water to remove any debris. The gel pad will be ready to use when it is washed and dried.

*Gel pad will last for 15 days. See www.vivera.com.

PRECAUTIONS:

Do not apply to areas with open wounds or other damage to skin. Never use on areas that have been previously treated with any other medication. This product may irritate the skin. If irritation occurs, discontinue use. If the gel pad has been applied, it should be removed as soon as possible. Do not use on areas with open wounds or other damage to skin. Do not use on areas with open wounds or other damage to skin. Do not use on areas with open wounds or other damage to skin.



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FOR EXTERNAL USE ONLY.

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



MANUFACTURED FOR:
VIVERA PHARMACEUTICALS
2100 W. 10TH AVENUE
SANTA FE, NM 87505



REUSABLE, ZIPPER®
RESEALABLE

Product Label - Foil Pack

Zipper

DURABLE • REUSABLE • WASHABLE RESEALABLE PACKAGE! DURABLE • REUSABLE

• **WASHABLE**

VIVERA® NDC# 72380-183-03

PHARMACEUTICALS

SILTREX®

SILICONE GEL-PAD

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

DIRECTIONS FOR USE:

- 1) Wash your hands and the scar area with soap and water. Dry thoroughly.
- 2) **Cut the SILTREX 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 finger 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 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.

04000-01-P-FOIL

REV20180926

MANUFACTURED FOR: VIVERA PHARMACEUTICALS 11100 GREENSTONE AVE. SANTA FE SPRINGS, CA 90670

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

UNPRINTED

LOT# EXP DATE STAMPED

Zipper

DURABLE • REUSABLE • WASHABLE

RESEALABLE PACKAGE!

DURABLE • REUSABLE • WASHABLE

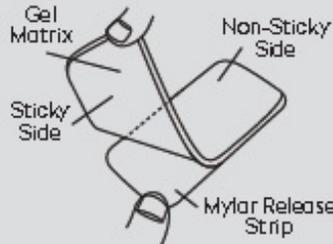


NDCF 7280-183-03

SILTREX[®]

SILICONE GEL-PAD

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



04-000-01 - P - PO IL
REV 20180928

MANUFACTURED FOR: VIVERA PHARMACEUTICALS 1100 GREGG STREET, DAVIS, CA 95618, USA
STORE AT 20°-25°C (68° TO 77°F); KEEP AWAY FROM HEAT AND PROTECT FROM FREEZING.

DIRECTIONS FOR USE

- 1) Wash your hands and the scar area with soap and water. Dry thoroughly.
- 2) Cut the Siltrex 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 (it is most effective to peel 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 8-12 hours per treatment. Wait 8-12 hours before reapplying to the next treatment.
- 5) When reapplying 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 new, use your finger to gently wash the gel pad with a little baby shampoo and water, if needed. Rinse with warm water and allow to 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 often or a strand would break may have been removed. It is not for use if the scar has been removed or if the skin has been removed. Do not use if you are allergic to the silicone or if the sticky side has been applied. If the product is applied to a burn or skin that is irritated, discontinue use and consult your physician. Always with dermatological diseases to ask or consult their physician before using this product.

Sealed side area 0.25" (qty4)

UNPRINTED

LOT# EXP DATE STAMPED

Product Label - Patient Insert



SILTREX[®]

SILICONE GEL-PAD

NDC# 72380-183-03

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

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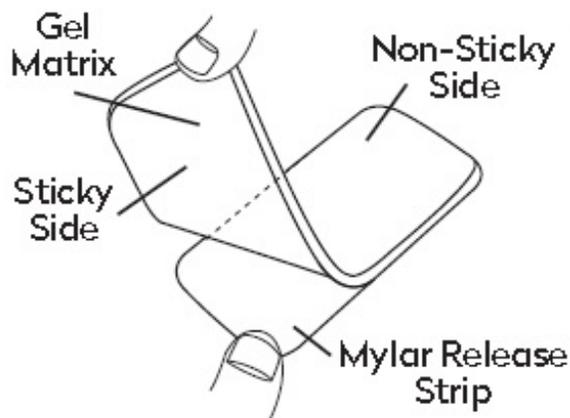
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SILTREX SILICONE GEL-PAD

elastomer, silicone, for scar management

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:72380-183
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:72380-183-03	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	10/01/2018	

Labeler - Vivera Pharmaceuticals, Inc. (081244342)

Registrant - Vivera Pharmaceuticals, Inc. (081244342)

Revised: 10/2018

Vivera Pharmaceuticals, Inc.