

**VIVERA SCARCARE PATCH WITH E-SCAR- elastomer, silicone, for scar management
Vivera Pharmaceuticals, Inc.**

VIVERA SCARCARE PATCH WITH E-SCAR

DIRECTIONS FOR USE:

- 1) Wash hands and the scar area with soap and water. Dry thoroughly.
- 2) Cut the ScarCare Gel-Pad™ to fit the scar area, as needed, so that the edges of the gel-pad extend at least 1/4" beyond the edge of the scar on all sides.
- 3) Gently peel the gel-matrix 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) Rub 1-2 drops of E-Scar Solution onto the scar when not wearing the gel-pad.
- 6) 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 antibacterial 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 seven (7) days with proper use and gentle care.

DIRECTIONS: Clean the area with soap and water. Let dry. Apply 1-2 drops onto the scar when not wearing the gel-pad. Massage gently until absorbed.

WARNINGS: If irritation develops, discontinue use and contact your physician.

PRECAUTIONS:

Do not apply to open wound or third degree burn. Never use on a sutured wound until the 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 has been 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 REACH OF CHILDREN.

FOR EXTERNAL USE ONLY.

INGREDIENTS: Dimethylpolysiloxane,
Dimethiconol, Cyclopentasiloxane,
Cyclotetrasiloxane, Tocopheryl Acetate,
(Vitamin E)

Principal Display Package

VIVERA

PHARMACEUTICALS

SCARCARE

GEL-PAK KIT

BY PRESCRIPTION ONLY

VIVERA NDC #72380-727-01

PHARMACEUTICALS MDA K001608

LOT NO.

SEE INDIVIDUAL COMPONENTS FOR EXP DATE

MEDICAL-GRADE SILICONE GEL MATRIX

(PATENTED FORMULA)

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

ONE (1) E-SCAR THERAPY SOLUTION - 15 mL (0.5 FL OZ)

DIRECTIONS FOR USE:

- 1) Wash hands and the scar area with soap and water. Dry thoroughly.
- 2) Cut the ScarCare Gel-Pad™ to fit the scar area, as needed, so that the edges of the gel-pad extend at least 1/4" beyond the edge of the scar on all sides.
- 3) Gently peel the gel-matrix 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) Rub 1-2 drops of E-Scar Solution onto the scar when not wearing the gel-pad.
- 6) 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 antibacterial 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 seven (7) days with proper use and gentle care.

PRECAUTIONS:

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KEEP OUT OF REACH OF CHILDREN.

FOR EXTERNAL USE ONLY.

STORE AT 20^o-25^o C (68^o TO 77^o F) KEEP AWAY FROM HEAT AND PROTECT FROM FREEZING

VIVERA

PHARMACEUTICALS

MANUFACTURED FOR:

VIVERA PHARMACEUTICALS

11100 GREENSTONE AVE.

SANTA FE SPRINGS, CA 90670

04000-01-P-BOX

REV 20180706

MEDICAL-GRADE SILICONE GEL MATRIX
(PATENTED FORMULA)
FOUR (4) GEL-PADS - 2" X 5.5" (NON-STERILE)
ONE (1) E-SCAR THERAPY SOLUTION® - 15mL (0.5FL. OZ.)

LOT NO.
SEE INDIVIDUAL COMPONENTS FOR EXP. DATE

NDC# 72380-727-01
NDA, K001608



BY PRESCRIPTION ONLY

SCARCARE
GEL-PAD KIT



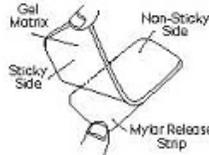
DIRECTIONS FOR USE:

- 1) Wash your hands and the scar area with soap and water. Dry thoroughly.
- 2) Measure the ScarCare 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-matrix pad from the mylar release strip (it is normal for small bits of the gel to remain on the mylar release strips). 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) Apply 1-2 drops of E-Scar Solution® onto the scar when not wearing the gel-pad. Massage gently until absorbed.
- 6) 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 anti-bacterial soap and water, or 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 seven (7) 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 cleaning 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.



MANUFACTURED FOR
VIVERA PHARMACEUTICALS
1800 GLENNVIEW AVE.
SANTA FE SPRING, CA 90670



04000-01-0-BOX
REV2018.07/04

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VIVERA NDC# 72380-727-01

PHARMACEUTICALS

E-SCAR

SCAR THERAPY

SOLUTION

15 mL (0.5 FL OZ)

INGREDIENTS: Dimethylpolysiloxane,
Dimethiconol, Cyclopentasiloxane,
Cyclotetrasiloxane, Tocopheryl Acetate,
(Vitamin E)

WARNINGS: If irritation develops,
discontinue use and contact your physician.

DIRECTIONS: Clean the area with soap
and water. Let dry. Apply 1-2 drops onto the
scar when not wearing the gel-pad. Massage
gently until absorbed.

Manufactured for:

Vivera Pharmaceuticals

11100 Greenstone Ave. 04000-01-PL-LBL

Santa Fe Springs, CA 90670 REV20180629

INGREDIENTS: Dimethylpolysiloxane,
Dimethiconol, Cyclopentasiloxane,
Cyclotetrasiloxane, Tocopheryl Acetate
(Vitamin E)

WARNINGS: If irritation develops,
discontinue use and contact your
physician.

The image shows the front of a product box for E-SCAR Scar Therapy Solution. At the top left is the VIVERA PHARMACEUTICALS logo. To its right is the NDC number 72380-727-01. The product name 'E-SCAR' is prominently displayed in large blue letters, with 'SCAR THERAPY SOLUTION' below it in smaller blue letters. At the bottom, a blue banner contains the volume '15 mL (0.5 FL OZ)'. The background of the box is white with blue and red accents.

DIRECTIONS: Clean the area with soap
and water. Let dry. Apply 1-2 drops onto the
scar when not wearing the gel-pad. Massage
gently until absorbed.

Manufactured for:
Vivera Pharmaceuticals
11100 Greenstone Ave.
Santa Fe Springs, CA 90670 04000-01-P-LBL
REV20180629

ZIPPER

**DURABLE • REUSABLE • WASHABLE RESEALABLE PACKAGE! DURABLE • REUSABLE
• WASHABLE**

VIVERA NDC# 72380-727-01

PHARMACEUTICALS MDA-K001608

SCARCARE

GEL-PAD KIT

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

DIRECTIONS FOR USE:

- 1) Wash hands and the scar area with soap and water. Dry thoroughly.
- 2) Cut the **ScarCare Gel-Pad™** to fit the scar area, as needed, so that the edges of the gel-pad extend at least 1/4" beyond the edge of the scar on all sides.
- 3) Gently peel the gel-matrix 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) Rub 1-2 drops of **E-Scar Solution** onto the scar when not wearing the gel-pad.
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MANUFACTURED FOR VIVERA PHARMACEUTICALS, 11100 GREENSTONE AVE., SANTA FE SPRINGS, CA 90670

STORE AT 20^o-25^o C (68^o TO 77^o F) KEEP AWAY FROM HEAT AND PROTECT FROM FREEZING

KEEP OUT OF REACH OF CHILDREN.

FOR EXTERNAL USE ONLY.

04000-01-P-FOL

REV20180706

UNPRINTED

LOT # EXP DATE STAMPED

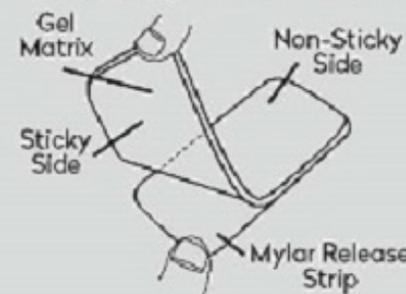
Zipper

DURABLE • REUSABLE • WASHABLE RESEALABLE PACKAGE! DURABLE • REUSABLE • WASHABLE



SCARCARE
GEL-PAD KIT

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



NDIC# 72380-727-01
MDA-K001608

DIRECTIONS FOR USE

- 1) Wash your hands and the scar area with soap and water. Dry thoroughly.
- 2) Cut the ScarCare Gel-Pad™ to fit the scar area, as needed, so that the edges of the gel-pad extend at least 1/4" beyond the scar on all sides.
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- 7) 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.

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PRECAUTIONS

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Sealed side area 0.25" (qty 4)

04000-01-P-FOL MANUFACTURED FOR: VIVERA PHARMACEUTICALS 1100 GREENSTONE AVE, SANTA FE SPRINGS, CA 90670
REV20180706 STORE AT 20°-25° C (68° TO 77° F). KEEP AWAY FROM HEAT AND PROTECT FROM FREEZING

UNPRINTED

LOT# EXP DATE STAMPED

res

VIVERA SCARCARE PATCH WITH E-SCAR

elastomer, silicone, for scar management kit

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		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	15 mL

Part 1 of 1

E-SCAR

dimethylpolysiloxane, dimethiconol, cyclopentasiloxane, cyclotetrasiloxane, tocopheryl acetate solution/ drops

Product Information

Item Code (Source)	NDC:72380-727
Route of Administration	TOPICAL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	3 mL in 15 mL

DIMETHICONOL (40 CST) (UNII: 343C7U75XW)	3 mg in 15 mL
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	3 mg in 15 mL
CYCLOMETHICONE 4 (UNII: CZ227117JE)	3 mg in 15 mL
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	3 mg in 15 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72380-727-01	1 in 1 PACKAGE		
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
premarket notification	K001608	07/01/2018		

Labeler - Vivera Pharmaceuticals, Inc. (081244342)

Registrant - Blaine Labs Inc. (017314571)

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