

**REVIVA-SIL- elastomer, silicone, for scar management**  
**Trifluent Pharma LLC**

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**REVIVASIL™ GEL- PAD KIT**

**USES**

RevivaSil™ Gel-Pad Kit 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.

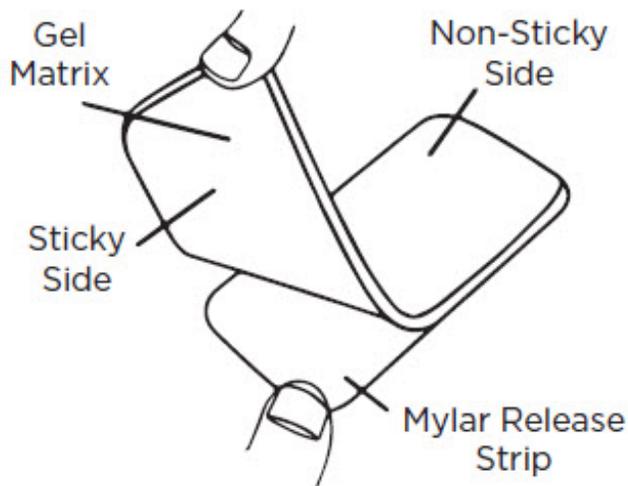
Discoloration of skin covered by gel-pad may temporarily occur in patients with darker complexions.

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 RevivaSil™ 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 (12 hours is recommended). Wait 8-12 hours without use before next treatment.
- 5) After removal of the gel-pad, apply 1-2 drops of Reviva-E™ onto the scar; massage gently until absorbed. Repeat as needed.
- 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 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 FACTS

Active Component	Purpose
Patented Silicone Gel Matrix Pad	Skin Scar Treatment

## COMPONENTS

Silicone Gel Matrix Pad (3" X 5.5")

Engineered as a self-adhesive pad; there is no need for additional wraps or taping. The non-sticky side is smooth and soft to prevent fabrics from adhering.

## DIRECTIONS

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

- 2) Cut the RevivaSil™ 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 (12 hours is recommended). Wait 8-12 hours without use before next treatment.
- 5) After removal of the gel-pad, apply 1-2 drops of Reviva-E™ onto the scar; massage gently until absorbed. Repeat as needed.
- 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 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.

## **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.

## **PRINCIPAL DISPLAY PANEL - Kit Label**

TRIFLUENT  
PHARMA®

RevivaSil™  
GEL-PAD KIT

QUESTIONS OR COMMENTS:  
CALL (210) 944-6920

MANUFACTURED FOR:  
Trifluent Pharma, LLC  
San Antonio, TX 78213

MADE IN THE U.S.A.  
540-01 REV02 12-22-2023

CONTAINS:  
FOUR (4) SILICONE GEL-PADS (3" X 5.5") (NON-STERILE)  
ONE (1) REVIVA-E™ SOLUTION – 0.5 FL. OZ. (15 mL)

PRODUCT SHOULD BE ADMINISTERED UNDER THE  
SUPERVISION OF A LICENSED MEDICAL PRACTITIONER  
(CONTENTS NOT FOR INDIVIDUAL SALE OR DISTRIBUTION)

NDC 73352-540-01



PRODUCT SHOULD BE ADMINISTERED UNDER THE SUPERVISION OF A LICENSED MEDICAL PRACTITIONER (CONTENTS NOT FOR INDIVIDUAL SALE OR DISTRIBUTION)



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MANUFACTURED FOR:  
Trifluent Pharma, LLC  
San Antonio, TX 78213

MADE IN THE U.S.A.  
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ONE (1) REVIVA-E™ SOLUTION – 0.5 FL. OZ. (15 mL)**

**NDC 73352-540-01**

PRODUCT FACTS	
<b>ACTIVE COMPONENT</b> PATENTED SILICONE GEL MATRIX PAD	<b>PURPOSE</b> SKIN SCAR TREATMENT
<b>COMPONENTS</b> Silicone Gel Matrix Pad (3" x 5.5") Engineered as a self-adhesive pad, there is no need for additional wraps or taping. The non-sticky side is smooth and soft to prevent fabrics from adhering. Reviva-E™ (Scar Therapy Solution with vitamin E)	
<b>DIRECTIONS</b> 1. Wash your hands and the scar area with soap and water. Dry thoroughly. 2. Cut the RevivaSil™ 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. 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 gel-pad 8-12 hours per treatment (12 hours is recommended). Wait 8-12 hours without use before next treatment. 5. After removal of the gel-pad, apply 1-2 drops of Reviva-E™ onto the scar; massage gently until absorbed. Repeat as needed. 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 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.	
<b>PRECAUTIONS</b> Do not apply to an open wound or 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 - 15 mL Bottle Label**

ADMINISTERED BY PRACTITIONER

TRIFLUENT  
PHARMA®

Reviva-E™

SCAR THERAPY  
SOLUTION WITH VITAMIN E

0.5 FL OZ (15 mL)

ADMINISTERED BY PRACTITIONER

**INGREDIENTS:** Butylene Glycol, Cyclopentasiloxane, Cyclotetrasiloxane, Dimethicone, Dimethiconol, Propylene Glycol, Tocopherol

**WARNINGS:** Stop use and ask a doctor if irritation develops.



**Reviva-E™**

SCAR THERAPY  
SOLUTION WITH VITAMIN E

0.5 FL OZ (15 mL)

**DIRECTIONS:** Wash your hands and the scar area with soap and water. Dry thoroughly. Apply 1-2 drops onto the scar, massage gently until absorbed. Repeat as needed.

**MANUFACTURED FOR:**  
Trifluent Pharma, LLC  
San Antonio, TX 78213  
CALL (210) 944-6920  
REV01 12-28-2023

## REVIVA-SIL

elastomer, silicone, for scar management kit

### Product Information

<b>Product Type</b>	MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:73352-540
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:73352-540-01	1 in 1 BOX		

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
<b>Part 1</b>	4 POUCH	4
<b>Part 2</b>	1 BOTTLE, DROPPER	15 mL

## Part 1 of 2

## REVIVASIL

elastomer, silicone, for scar management patch

### Product Information

<b>Route of Administration</b>	TOPICAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	12 h

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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
EXEMPT DEVICE	MDA	12/25/2023	

## Part 2 of 2

### REVIVA-E

elastomer, silicone, for scar management solution/ drops

### Product Information

**Route of Administration** TOPICAL

### Inactive Ingredients

Ingredient Name	Strength
<b>DIMETHICONE 100</b> (UNII: RO266O364U)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>CYCLOMETHICONE 4</b> (UNII: CZ227117JE)	
<b>DIMETHICONOL (40 CST)</b> (UNII: 343C7U75XW)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

### Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
EXEMPT DEVICE	MDA	12/25/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
EXEMPT DEVICE	MDA	12/25/2023	

**Labeler** - Trifluent Pharma LLC (117167281)

Revised: 2/2024

Trifluent Pharma LLC