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

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.

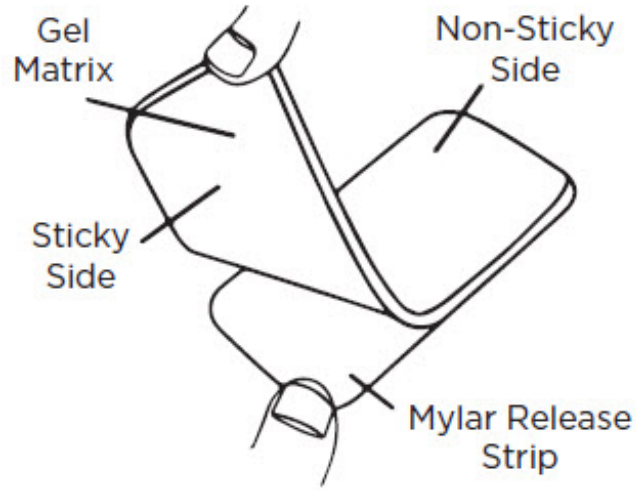
Discoloration of skin covered by gel-pad may temporarily occur in patients with darker complexions.

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.
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PRECAUTIONS

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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

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)

REVIVA-SIL

elastomer, silicone, for scar management kit

Product Information			
Product Type	MEDICAL DEVICE	**Item Code (Source)**	NHRIC:73352-540

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**
Part 1	4 POUCH	4
Part 2	1 BOTTLE, DROPPER	15 mL

Part 1 of 2

REVIVASIL

elastomer, silicone, for scar management patch

Product Information	
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (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
DIMETHICONE 100 (UNII: RO266O364U)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
DIMETHICONOL (40 CST) (UNII: 343C7U75XW)	
TOCOPHEROL (UNII: R0ZB2556P8)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PROPYLENE GLYCOL (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