

CICATRACE PAD- elastomer, silicone, for scar management patch
TMIG Inc

CICATRACE PAD
(Silicone Gel Matrix)

Rx only

For external use only
Not for ophthalmic use

CICITRACE PAD Description

CICITRACE PAD is intended for non-invasive management of old and new hypertrophic or keloid scars resulting from burns, surgical procedures or trauma wounds.

Each **CICITRACE PAD** contains: Silicone, Polydimethyl hydrogenmethyl siloxane, Polydimethylsiloxane, and Polydimethylsiloxane hydrogen terminated.

CICITRACE PAD - Clinical Pharmacology

The exact mechanism of silicone gel in improving the appearance of scar tissue remains unknown. However, numerous mechanisms have been suggested to explain the efficacy of silicone gel, including hydration, pressure, temperature, oxygen transmission and silicone absorption. There is some evidence that the treatment affects the stratum corneum and, by reducing evaporation, restores better homeostasis in the tissue. In keloid and hypertrophic scarring, the stratum corneum allows more evaporation of water from the underlying tissue than occurs in normal skin. Silicone pads may prevent this, keeping the stratum corneum in optimal hydration and protecting the skin from environmental hazards, both of which can reduce abnormal scarring. The gel may also affect the stratum corneum by inhibiting mast cell activity, diminishing edema, vasodilatation and excessive extracellular matrix formation but the simple changes in temperature, pressure, oxygen tension and hydration produced by wound coverage probably constitute the main mechanism of action. Another hypothesis is that the effect of static electricity on silicone may influence the alignment of collagen deposition.

INDICATIONS AND USES

For non-invasive management of old and new hypertrophic or keloid scars resulting from burns, general surgical procedures, injuries or trauma wounds.

Contraindications

CICITRACE PAD is contraindicated in patients with known hypersensitivity to silicone or any of the listed ingredients.

Warnings

For external use only. Avoid contact with eyes, lips or mucous membranes. Do not apply on areas of broken skin. Do not apply on third degree burns and open wounds. Never use on sutured wound until sutures have been removed.

Precautions

Stop use and ask a doctor if irritation develops. 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. If ingested, get medical help or contact Poison Control Center right away. **KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.**

This medication should be used as directed by your physician during pregnancy or while breast-feeding. Consult your doctor about the risks and benefits.

Adverse Reactions

Rarely the Pads may cause transient redness stinging, burning or irritation and normally disappear on discontinuing the medication.

CICITRACE PAD - Dosage and Administration

- 1-Wash your hands and the scar area with soap and water. Dry thoroughly.
- 2-Cut the CICITRACE Pad to fit the scar area so that the edges of the gel pad extend at least 1/4 inch beyond the scar on all sides.
- 3-Peel of the strip and place the sticky side of the pad directly onto the scar. Leave on for 8-12 hours per day then remove. Do not discard the mylar release strip.
- 4-When not wearing the pad, place the gel pad (sticky side) back onto the mylar release strip.
- 5-Discard the pad and replace with a new one every 7 days.

How is CICITRACE PAD Supplied

CICITRACE PAD (Silicone Gel Matrix) is supplied in:

TWO (2) Large Non-Sterile Silicone Gel Pads – 4.7" × 5.7" in 1 Carton	69176-0518-02
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Store at 20°-25°C (68° to 77°F); Keep away from heat and protect from freezing. [See USP Controlled Room Temperature.]

PRINCIPAL DISPLAY PANEL - 2 Pad Pouch Carton

TMIG Inc.

NDC 69176-0518-02

CICITRACE PAD

TWO (2) Gel Pad - 4.7' x 5.7" (Non - Sterile)

SILICONE GEL MATRIX

RX ONLY



NDC 69176-0518-02



CICATRACE PAD

Silicone gel matrix sheeting

Contains 2 Gel-pads (Non-Sterile) Each
4.7 in High
5.7 in Wide
.04 in Thick

- Ideally dimensioned for medium to large scars from burns, road rash, or keloid and hypertrophic scars from surgery or trauma
- The most comfortable silicone sheeting in the industry! Significantly thinner than competitors, allowing CicatrAce to conform precisely to body contours
- Clinically proven to reduce, flatten, fade and smooth scars -- both old and new
- Helps prevent the formation of new scars
- FDA Class 1 medical device used in hospitals and clinics
- 100% medical grade silicone
- Washable & reusable

Ref: ABC-1234

Manif: 01 2018

Exp: 12 2022

Lot: 1234

Packaged in the USA for, and Distributed by:

TMIG Inc, Marietta, GA 30062

Product sales or info call 770-579-8883

Tmigsales@gmail.com





NDC 69176-0518-02



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Product Information

Product Type

MEDICAL DEVICE

Item Code (Source)

NHRIC:69176-0518

Route of Administration

TOPICAL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69176-0518-2	2 in 1 CARTON		
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	K003948	06/14/2018	

Labeler - TMIG Inc (036572986)

Revised: 6/2018

TMIG Inc