SCARCIN PAD- elastomer, silicone, for scar management patch
SA3, LLC

SCARCIN PAD
SA3, LLC

SCARCIN PAD (Silicone Gel Matrix)
Rx only
For external use only
Not for ophthalmic use

SCARCIN PAD Description

SCARCIN PAD is intended for use in the management of closed hyperproliferative scars, both old and new hypertrophic or keloid scars resulting from burns, surgical procedures or trauma wounds.

Each **SCARCIN PAD** contains: Silicone, Polydimethylsiloxane, Vinyltriethoxysilane, Organotin catalyst, and pure water.

CLINICAL PHARMACOLOGY

The exact mechanism of action in improving the appearance of scar tissue from using silicone remains unknown. However, various suggestions have been made to explain the efficacy of silicone sheets, 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 use in the management of closed hyperproliferative (hypertrophic or keloid) scars.

CONTRAINDICATIONS

SCARCIN 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 breastfeeding. Consult your doctor about the risks and benefits.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

ADVERSE REACTIONS

On rare occasions, the Pads may cause temporary redness, stinging, burning or irritation and normally disappear when the medication is discontinued.

DOSAGE AND ADMINISTRATION

1. Wash hands and scar area thoroughly with soap and water. Completely dry the area after.
2. If needed, cut the SCARCIN PAD to size making sure to leave at least 1/4” beyond the area of the scar.
3. Peel off the backing of the sheet and place it sticky side down on the affected area.
4. For best results, leave on for 8-12 hours. When finished, dispose of sheet.
5. Change gel pad once a day until no longer needed.

How is SCARCIN PAD Supplied

SCARCIN PAD (Silicone Gel Matrix) is supplied in:
Seven (7) Large Non-Sterile Silicone Gel Pads – 1.57" × 5.12" in 1 Carton
NDC: 69420-8001-1

Store at 20°-25°C (68° to 77°F); Keep away from heat and protect from freezing. [See USP Controlled Room Temperature.]

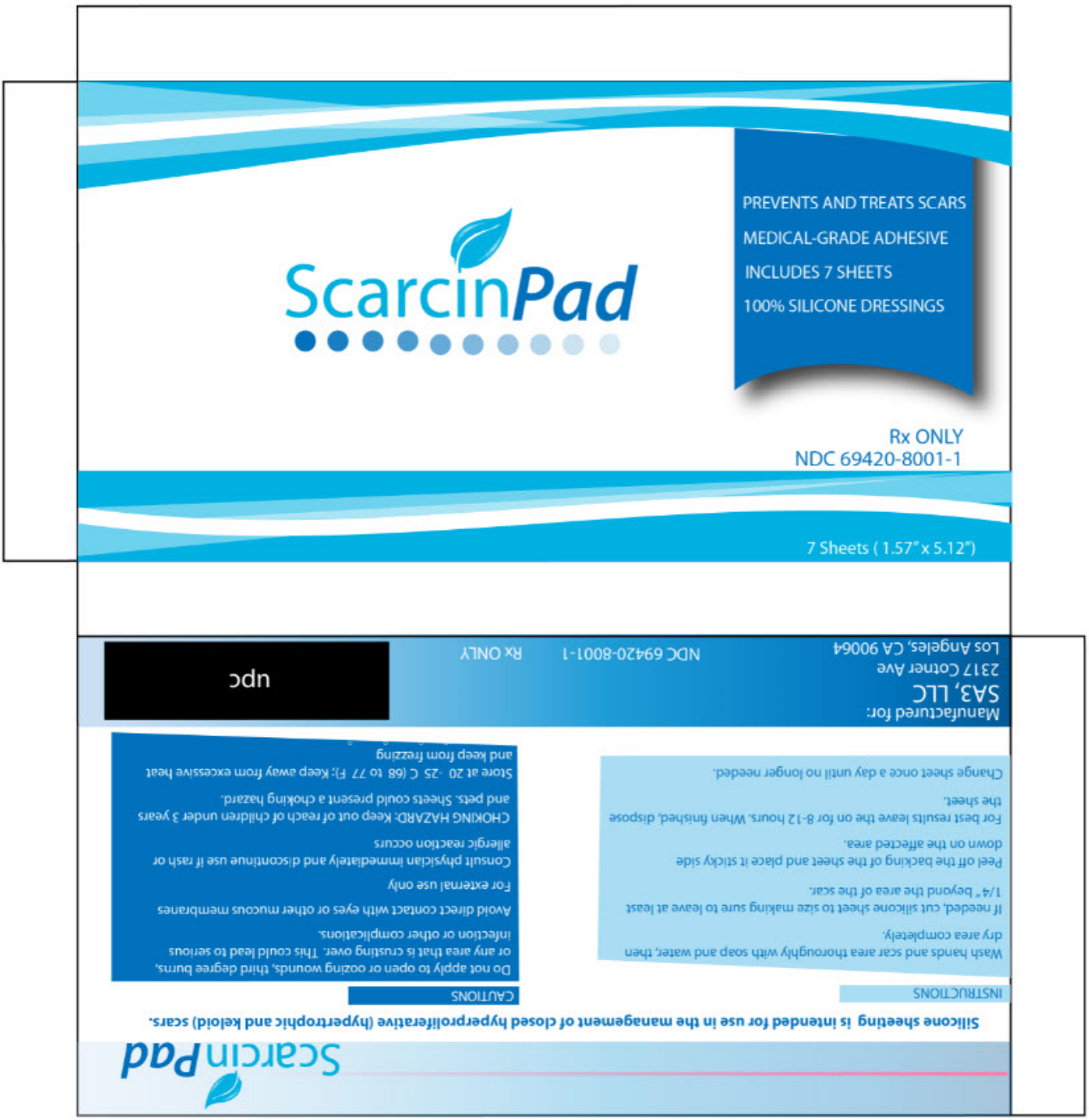
Manufactured for:
SA3, LLC
Los Angeles, CA 90064

PRINCIPAL DISPLAY PANEL

NDC 69420-8001-1

Rx ONLY

Scarcin*Pad*



SCARCIN PAD

elastomer, silicone, for scar management patch

Product Information			
Product Type	MEDICAL DEVICE	**Item Code (Source)**	NHRIC:69420-8001
Route of Administration	TOPICAL		

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NHRIC:69420-8001-1	7 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
EXEMPT DEVICE	MDA	10/01/2018	

Labeler - SA3, LLC (079627454)

Revised: 9/2018 SA3, LLC