

PROSILK MEDICAL GRADE SILICONE SCAR PAD- elastomer, silicone, for scar management
NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY

ProSilk Pad

ProSilk Medical Grade Silicone Scar Pad
NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY
Rx only
For external use only
Not for ophthalmic use

NBGS PROSILK MEDICAL GRADE SILICONE SCAR PAD DESCRIPTION

ProSilk Medical Grade Silicone Scar 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 **PAD** contains: Medical Grade Silicone

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

ProSilk Medical Grade Silicone Scar 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. 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 ProSilk 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 per day.
5. Each sheet lasts 7 days, box contains 2 Weeks Supply.

HOW IS PROSILK MEDICAL GRADE SILICONE SCAR PAD SUPPLIED

ProSilk Medical Grade Silicone Scar Pad (Silicone Gel Matrix) is supplied in:

2 Non-Sterile Silicone Gel Pads – 5 cm × 14 cm in 1 Carton

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

Manufactured for:

NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY

PRINCIPAL DISPLAY PANEL



PROSILK MEDICAL GRADE SILICONE SCAR PAD

elastomer, silicone, for scar management

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:72678-006
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:72678-006-01	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
exempt device	MDA	07/15/2020	

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