

SCARCIN PAD PLUS- oral wound dressing gel
Beijing HKKY Medical Tech. Co., Ltd.

71073-213_Scarcin Pad PLUS

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 PLUS 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 PLUS 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 PLUS Supplied

SCARCIN PAD PLUS (Silicone Gel Matrix) is supplied in:
Seven (7) Large Non-Sterile Silicone Gel Pads – in 1 Carton
NDC: 69420-8101-1

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

SCARCIN PAD PLUS
7 Sheets
Rx Only


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

CAUTIONS:
 Do not apply to open or oozing wounds, third degree burns, or any area that is crusting over. This could lead to serious infection or other complications.
 Avoid direct contact with eyes or other mucous membranes.
 For external use only.
 Consult physician immediately and discontinue use if rash or allergic reaction occurs.
CHOKING HAZARD: Keep out of reach of children under 3 years and pets. Sheets could present a choking hazard.
 Store at 20°-25° C (68° to 77° F); Keep away from excessive heat and keep from freezing.
CAUTION: Federal law restricts this device to sale by or on the order of a physician.
INGREDIENTS: Phenyl Trimethicone, Glycerol, Polyacrylic Acid, Stearic Acid, Tartaric Acid

Silicone sheeting is intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars.

Manufactured for:
SA3, LLC
 2317 Cotner Ave
 Los Angeles, CA 90064

69420-8101-1 Rx ONLY



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Scarcin Pad PLUS

Scarcin Pad PLUS

PREVENTS AND TREATS SCARS • MEDICAL-GRADE ADHESIVE • INCLUDES 7 SHEETS • SILICONE DRESSINGS

Rx ONLY 7 Sheets

Scarcin Pad PLUS

SCARCIN PAD PLUS

oral wound dressing gel

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:71073-213
Route of Administration	TOPICAL		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:71073-213-01	7 in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Exempt device	MDA	09/05/2021	

Labeler - Beijing HKKY Medical Tech. Co., Ltd. (544434817)

Establishment

Name	Address	ID/FEI	Business Operations
Beijing HKKY Medical Tech. Co., Ltd.		544434817	manufacture

Revised: 9/2021

Beijing HKKY Medical Tech. Co., Ltd.