

SILIVEX- elastomer, silicone, for scar management
Sterling-Knight Pharmaceuticals, LLC

Silivex
(Silicone Scar Pad)

Rx only

For external use only
Not for Ophthalmic use

Silivex Silicone Scar Pad Description

Silivex Silicone pad is a soft, thin, reusable and self-adhesive silicone gel sheet. It is effective for the management of both existing and new hypertrophic or keloid scars and as a prophylactic treatment on closed wounds to prevent hypertrophic or keloid scarring that may have resulted from burns, surgical procedures or trauma wounds.

Each Silivex Pad contains: Silicone gel matrix (Polydimethyl hydrogenmethyl siloxane, Polydimethylsiloxane, and Polydimethylsiloxane hydrogen terminated).

Silivex Silicone Scar 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 external use only. Temporary use in the management of both existing and new hypertrophic or keloid scars. Temporary use as a prophylactic treatment on closed wounds to prevent hypertrophic or keloid scarring. Do not use on open wounds.

CONTRAINDICATIONS

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

WARNINGS

For external use. Do not apply to an open wound or third degree burn. Never use on a sutured wound until sutures have been removed. In rare instances, silicone pad 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.

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.**

Call your doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088. **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

Caution:

Federal law restricts this device to sale by or on the order by a licensed healthcare practitioner.

ADVERSE REACTIONS

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

DOSAGE AND ADMINISTRATION

1. Wash your hands and the scar area with soap and water. Dry thoroughly.
2. Cut the Silivex Pad to fit the scar area so that the edges of the gel pad extend at least 1/4" 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 SUPPLIED

Silivex Pad is supplied in:

Four (4) Large Non-Sterile Silicone Gel Pad – 2” x 5.5” in 1 Carton, NDC 69336-802-04

Two (2) Large Non-Sterile Silicone Gel Pad – 2” x 5.5” in 1 Carton, NDC 69336-802-02

STORAGE

Store at controlled room temperature 15°-30°C (59°F-86°F). Keep in cool dry place. Protect from light and moisture.

Distributed By:

Sterling-Knight Pharmaceuticals, LLC

Ripley, MS 38663

Rev 0618-1

PRINCIPAL DISPLAY PANEL - 4 Pad Pouch Carton



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 Rev 0618-1

Silivex
Silicone Scar Pad
Prescription Only

SILIVEX
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Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:69336-802
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69336-802-04	4 in 1 CARTON		
1		1 in 1 POUCH; Type 1: Convenience Kit of Co-Package		
2	NHRIC:69336-802-02	2 in 1 CARTON		
2		1 in 1 POUCH; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K083718	07/30/2018	

Labeler - Sterling-Knight Pharmaceuticals, LLC (079556942)

Establishment

Name	Address	ID/FEI	Business Operations
Sterling-Knight Pharmaceuticals, LLC		079556942	manufacture

Revised: 9/2018

Sterling-Knight Pharmaceuticals, LLC