

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

KelaRx
Scar Care Gel

KelaRx™
Scar Care Gel
Prescription Only

KelaRx Scar Care Gel Description

For Old and New Scars

- Reduces redness
- Softens and flattens raised scars
- Relieves itching, discomfort and pain associated with scars
- Helps prevent excessive and abnormal scar formation
- For use as mono-therapy or in combination with other scar therapies, including pressure garments.

KelaRx™ is a self-drying, flexible, gas permeable, waterproof silicone gel that is colorless and odorless. KelaRx™ forms a bond with the stratum corneum (the outer layer of dead skin cells) forming a protective barrier against chemical physical and microbial invasion of the scar site while assisting with hydration.

KelaRx™ is also for use on children or people with sensitive skin. Silicone Gel Sheets are internationally recommended as the first line of treatment in scar management.

Ingredients:

Dimethicone, Dimethicone Crosspolymer, Trimethylsiloxysilicate.

INDICATIONS

KelaRx™ is intended for the management of old and new scars, including hypertrophic and keloid scars, resulting from general surgical procedures, trauma, wounds and burns.

WARNINGS

Avoid direct contact with eyes, mucous membranes, third degree burns and open wounds. KelaRx™ should not be used on dermatological conditions that disrupt the integrity of the skin. For external use only. If irritation occurs, discontinue use and consult your physician. Keep this product out of the reach of children. Store below 25°C/77°F.

PRECAUTIONS

Caution:

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

CALL YOUR DOCTOR ABOUT SIDE EFFECTS.

Call your doctor about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

DOSAGE AND ADMINISTRATION

Ensure that the affected area is clean and dry. Apply KelaRx™ to the area as a very thin coat and allow to dry. Apply KelaRx™ twice daily. Once dry, KelaRx™ can be covered with cosmetics or sunscreen. Recommended duration of treatment 60-90 days.

HOW SUPPLIED

KelaRx™ Scar Care Gel is supplied as a white gel in:
30 g tube, NDC 69336-803-30

Distributed By:

Sterling-Knight Pharmaceuticals, LLC
Ripley, MS 38663

Made in USA
Rev 0518-1

PRINCIPAL DISPLAY PANEL





NDC 69336-803-30

KelaRx

(Silicone)

Prescription Scar
Care Gel



30g

Rx Only

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Distributed by:
Sterling-Knight Pharmaceuticals, LLC
Ripley, MS 38663

Made in USA



Item # 803
Rev 0518-01

Sterling-Knight Pharmaceuticals, LLC

Ripley, MS 38663

Made in USA

Rev 0518-1

KelaRx™

Scar Care Gel

Prescription Only

KELARX

elastomer, silicone, for scar management

Product Information

| | | | |
|---------------------|----------------|---------------------------|-----------------|
| Product Type | MEDICAL DEVICE | Item Code (Source) | NHRIC:69336-803 |
|---------------------|----------------|---------------------------|-----------------|

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| DIMETHICONE/DIENE DIMETHICONE CROSSPOLYMER (UNII: RSA9I561OK) | |
| TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|--------------------|--|----------------------|--------------------|
| 1 | NHRIC:69336-803-30 | 1 in 1 CARTON | | |
| 1 | | 1 in 1 TUBE; 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 | 06/29/2018 | |

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