**KELOTOP SILICONE GEL FOR SCARS -DIMETHYL METHYLVINYL SILOXANE-elastomer, silicone, for scar management**
**AMELLA PHARMA, LLC**

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**KELOTop®**

**KELOTOP® SILICONE GEL – DIMETHYL METHYLVINYL SILOXANE– ELASTOMER, SILICONE, FOR SCAR MANAGEMENT**

**Rx Only**

For external use only

Not for ophthalmic use

## INDICATIONS

KELOTOP® Silicone Gel is intended for use in the management, control and prevention of old and new hypertrophic or keloid scars resulting from burns or surgical or traumatic injury of the skin, by forming an occlusive barrier.

## CONTRAINDICATIONS

Do not use on open wounds or when any Dermatological conditions disrupt the skin (such as a rash and/or burns).

KELOTOP® Silicone Gel is contraindicated in patients with known hypersensitivity to silicone or any of the listed ingredients.

## WARNINGS, PRECAUTIONS, ADVERSE REACTIONS

Possible complications include:

- Superficial maceration of the skin
- Rash
- Skin Discoloration
- Pruritus

Rashes have been observed on skin under the KELOTOP® Silicone Gel, this has been attributed to poor or insufficient cleansing of the scar area. Should a rash occur, stop using the KELOTOP® Silicone Gel for 12 hours followed by using the KELOTOP® Silicone Gel for 12 hours. If the rash persists, a physician should be contacted and KELOTOP® Silicone Gel use should be discontinued.

Discoloration of the skin covered by KELOTOP® Silicone Gel has been reported, particularly in dark skinned patients. This effect appears to be transient, and may be similar to the discoloration experienced whenever an area of skin is covered for extended periods of time.

**If ingested, get medical help or contact Poison Control Center right away.**

Do not use creams, lotions, sun block or other silicone products over and around the scar area when wearing KELOTOP® Silicone Gel. These products will create a barrier between the scar site and the silicone gel, preventing a proper healing environment.

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

**Precautions:**

**1.** Do not apply to an open wound or third degree burn.

**2.** Never use on a sutured wound until sutures have been removed.

**3.** In rare instances Silicone Gel may cause a rash on the skin. This condition may result from improper cleaning of the scar area. Should the skin irritation still occur, discontinue use and consult your physician.

**4.** It is not recommended that this product be used on children under six months of age.

**INGREDIENTS**

Each KELOTOP® Silicone Gel contains: Dimethyl Methylvinyl Siloxane.

**INSTRUCTIONS FOR USE:**

1. Wash both scar and hands per cleaning instructions. Ensure the scar site is dry prior to each application.
2. Apply KELOTOP® Silicone Gel liberally over the entire scar area. It is recommended that this procedure be repeated several times daily for 8-12 weeks or until scar stops responding.
3. KELOTOP® Silicone Gel once applied will have a “tacky” appearance and feel which is natural and to be expected.
4. To remove, wipe off with a clean cloth or tissue.

**CLEANING INSTRUCTIONS** Every 12 hours the scar area should be washed. First wipe KELOTOP® Silicone Gel off the scar area with a clean cloth or tissue. Then gently wash the scar area with soapy water, rinse, and then let air dry.

**WEARING TIME** Optimal wearing time for KELOTOP® Silicone Gel is 24 hours per day. If it is not possible to wear the KELOTOP® Silicone Gel for the recommended 24 hour period, a minimum of 12 hours per day is required, washing per the instructions above once in that period. Follow this procedure each day, washing and re-applying the KELOTOP® Silicone Gel several times daily. The overall optimal period of use is usually 8 to 12 weeks or until scar stops responding.

**HOW IT IS SUPPLIED**

KELOTOP® Silicone Gel are supplied as a clear gel. Non-sterile product is labeled as such and supplied in a protective package within a protective outer container.

KELOTOP® Silicone Gel is available as the following:

NDC 72287-416-10 10gm tube

**Store at 55°-95°F (13°-35°C); Keep away from heat and protect from freezing. Do not refrigerate.**

**NON-STERILE**

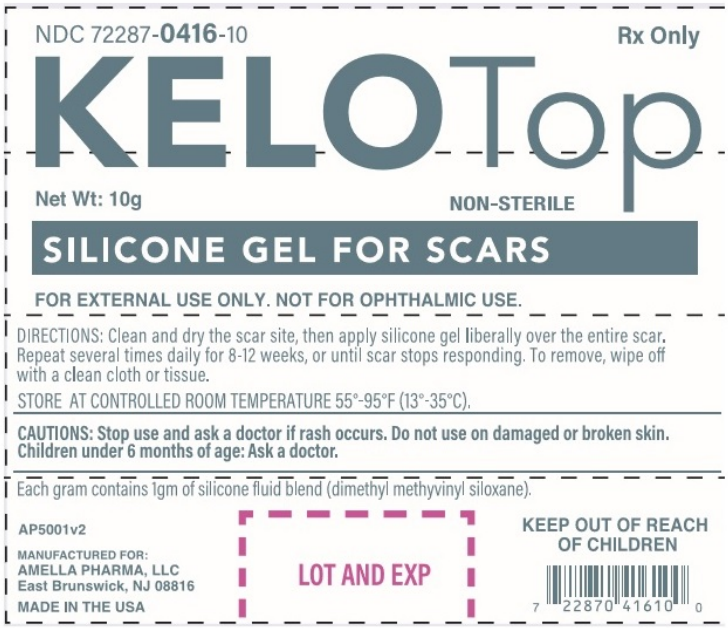
Manufactured for:
Amella Pharma, LLC
East Brunswick, NJ 08816

12/2018 AP-5002v1
KELOTOP® is a registered Trademark of Amella Pharma, LLC

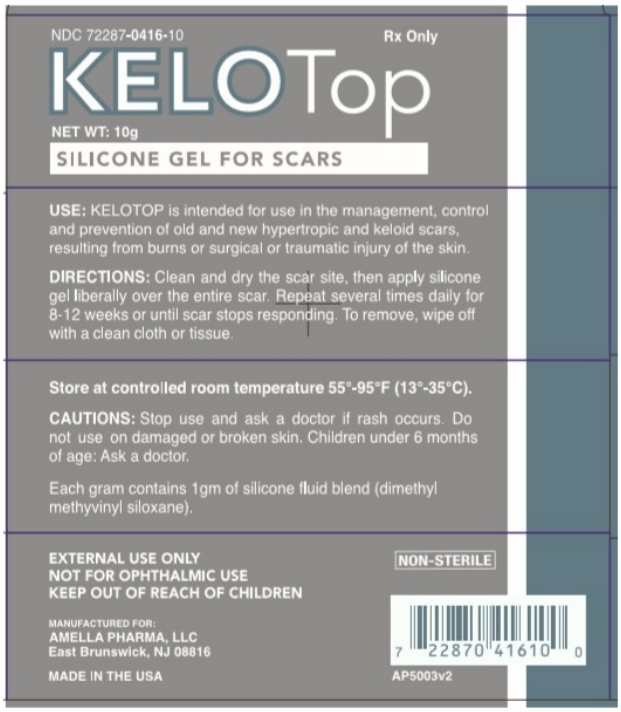
MADE IN THE USA

**Packaging**

**INNER TUBE LABEL**




**OUTER BOX LABEL**




# KELOTOP SILICONE GEL FOR SCARS -DIMETHYL METHYLVINYL SILOXANE

elastomer, silicone, for scar management

| Product Information | | | |
|---|---|---|---|
| **Product Type** | MEDICAL DEVICE | **Item Code (Source)** | NHRIC:72287-416 |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NHRIC:72287-416-10 | 1 in 1 BOX | | |
| **1** | | 10 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| premarket notification | K003948 | 12/15/2018 | |

**Labeler -** AMELLA PHARMA, LLC (081189492)

Revised: 12/2018 AMELLA PHARMA, LLC