KELOTOP SILICONE STICK FOR SCARS- elastomer, silicone, for scar management
AMELLA PHARMA, LLC

KELOTop®

KELOTOP® SILICONE STICK – ELASTOMER, SILICONE, FOR SCAR MANAGEMENT

Rx Only

For external use only

Not for ophthalmic use

INDICATIONS

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

Discoloration of the skin covered by KELOTOP® Silicone Stick 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 Stick. These products will create a barrier between the scar site and the KELOTOP® Silicone Stick, 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 Stick 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 Stick contains: Dimethyl Methylvinyl Siloxane gel, Beeswax, Paraffin Wax, Octyldodecanol, Tocopheryl Acetate (Vitamin E), Bisabolol, EDTA.

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 Stick 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 Stick 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 Stick 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 Stick is 24 hours per day. If it is not possible to wear the KELOTOP® Silicone Stick 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 Stick 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 Stick is a non-sterile product and labeled as such and supplied in a protective package within a protective outer container.

KELOTOP® Silicone Stick is available as the following:

NDC 72287-417-04 4.25gm Stick

NDC 72287-417-17 17gm Stick

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

NON-STERILE

U.S Patent No. 8,557,287

Manufactured for:

Amella Pharma, LLC

East Brunswick, NJ 08816

MADE IN THE USA

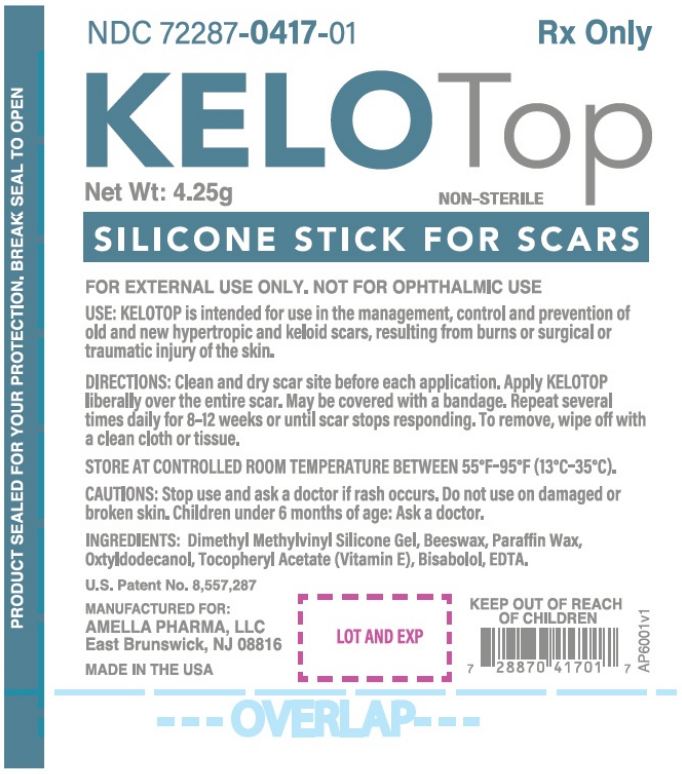
12/2018 AP-6002v1

KELOTOP® is a registered Trademark of Amella Pharma, LLC

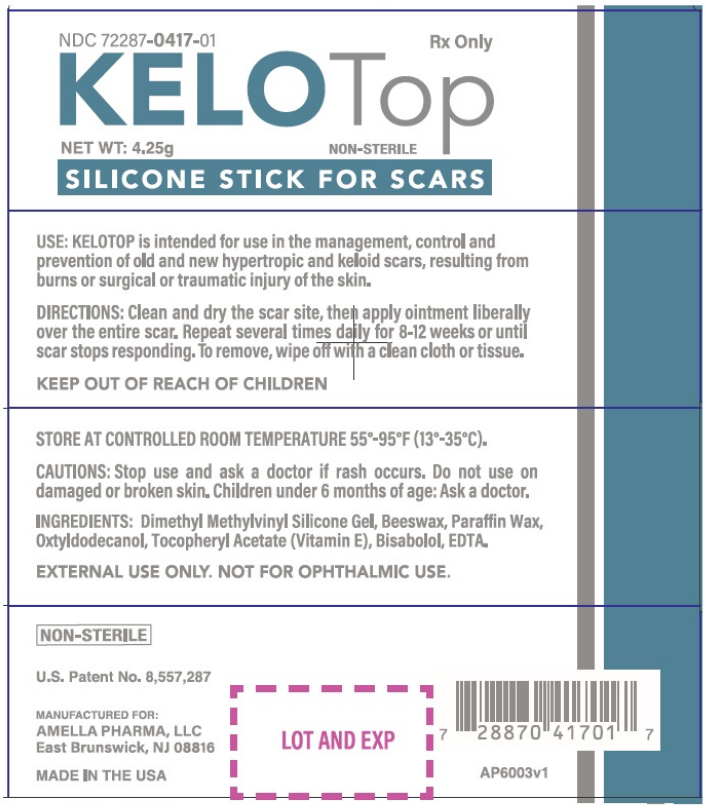
Packaging

KELOTOP STICK - 4.25 gm

INNER STICK LABEL



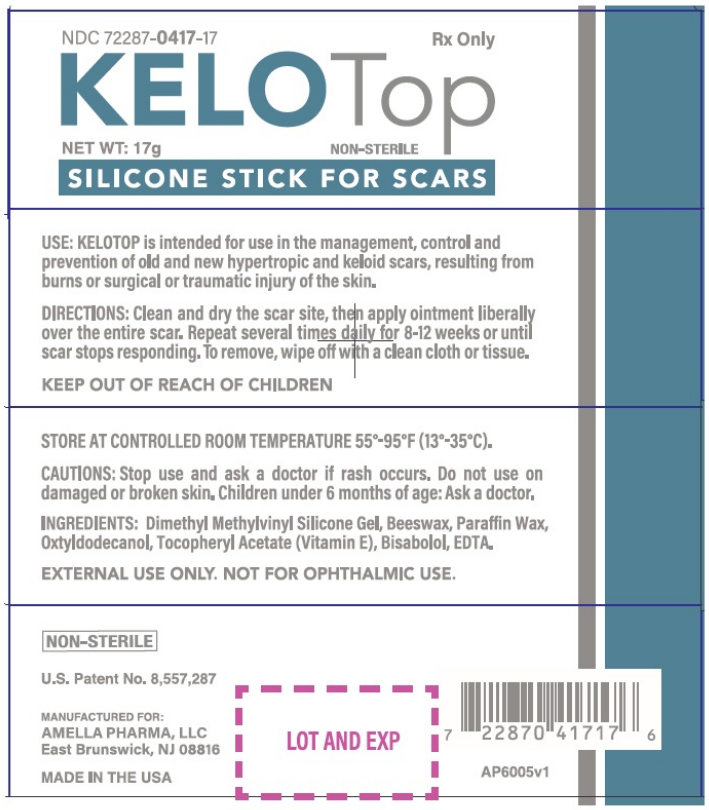
OUTER BOX LABEL



KELOTOP STICK - 17 gm

INNER STICK LABEL

OUTER BOX LABEL



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elastomer, silicone, for scar management

Product Information			
Product Type	MEDICAL DEVICE	**Item Code (Source)**	NHRIC:72287-417

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:72287-417-01	1 in 1 BOX		
1		4.25 g in 1 TUBE; Type 0: Not a Combination Product		
2	NHRIC:72287-417-17	1 in 1 BOX		
2		17 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