

NEWGEL PLUS SPF- zinc oxide, sunscreen gel
Newmedical Technology, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredients	
Purpose	
Zinc Oxide 20%.....	Sunscreen

Inactive Ingredients

Polymerized Siloxanes (Silicone Gel), C12-15 Alkyl Benzoate,
Polyhydroxystearic Acid

Warnings

For External use only

Keep out of reach of children

Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs.

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Active Ingredients

Purpose

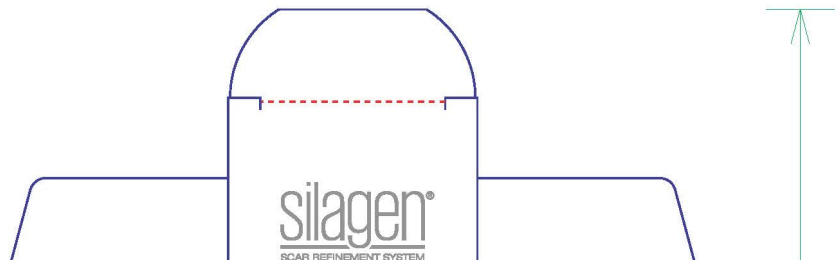
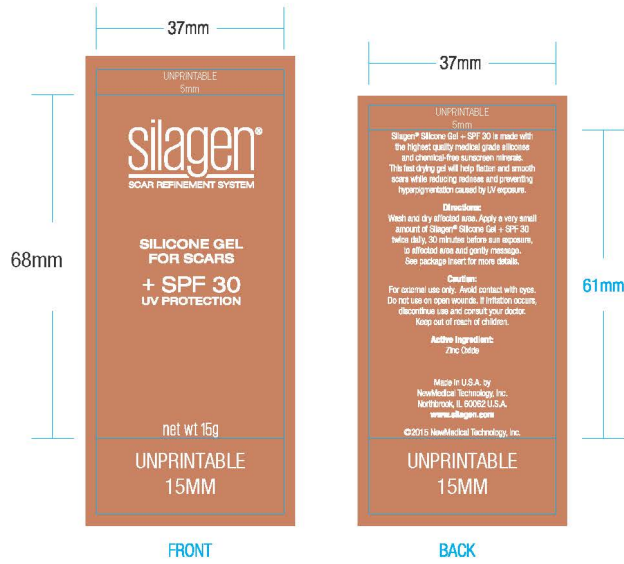
Zinc Oxide 20%.....Sunscreen

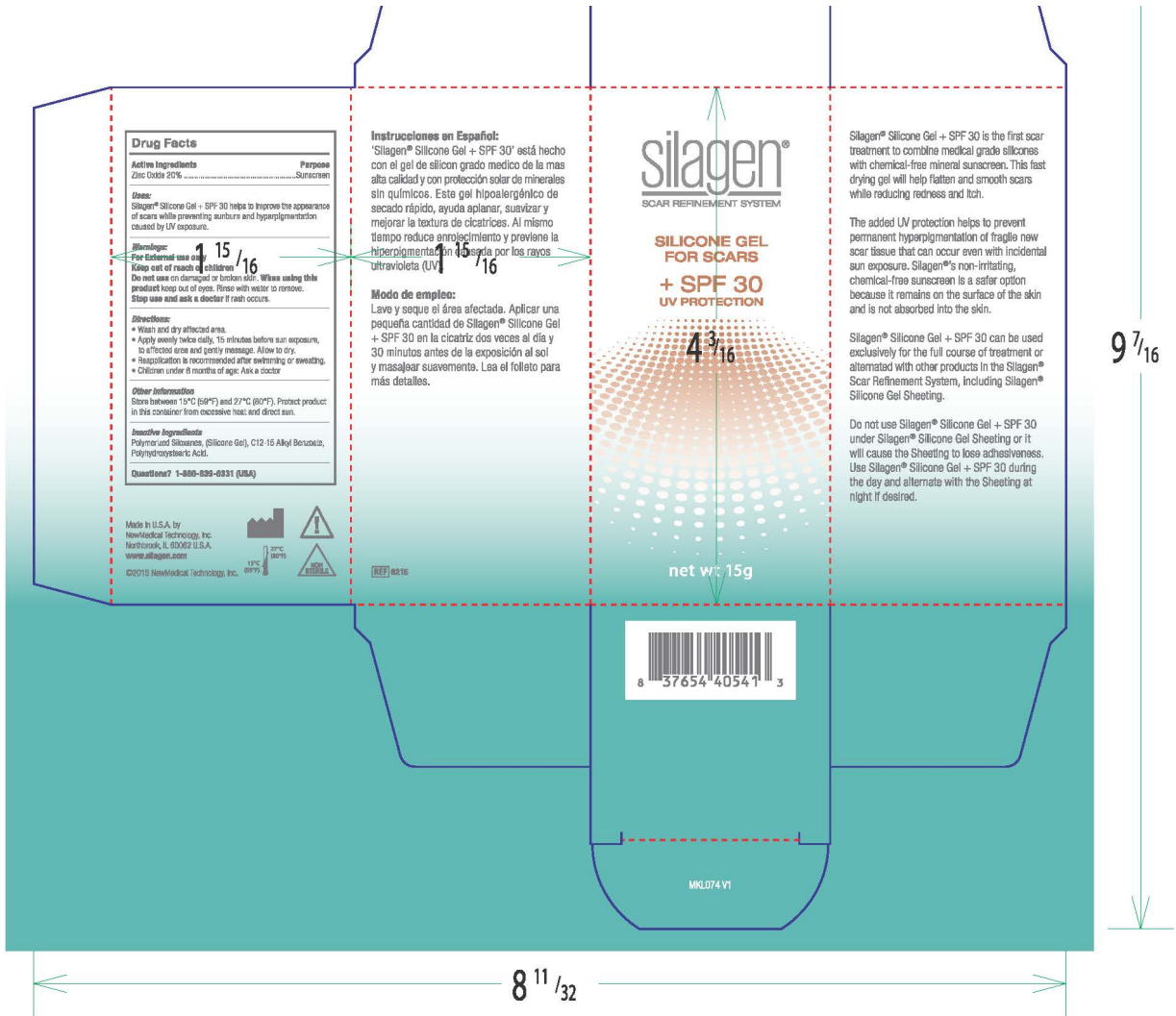


RT-15 Printing area

INNER WALL
LOGO + COPY
COLLAR/ACTUATOR

PMS 7591C
WHITE
SILVER METALLIZATION



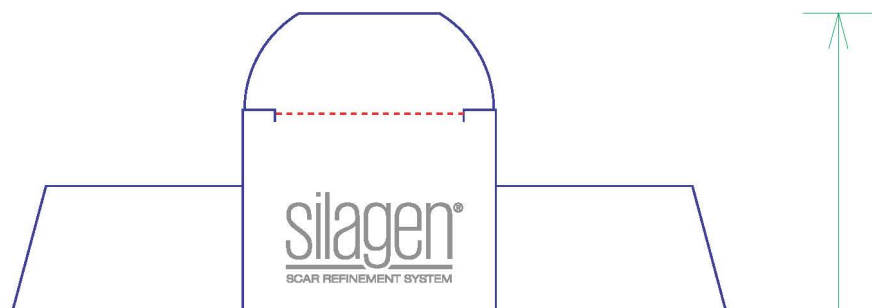
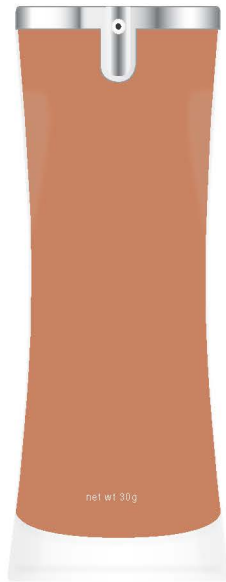




RT-30 Printing area

INNER WALL
LOGO + COPY
COLLAR/ACTUATOR

PMS 7591C
WHITE
SILVER METALLIZATION



Drug Facts

Active Ingredients Purpose
Zinc Oxide 20% Sunscreen

Uses:
Silagen® Silicone Gel + SPF 30 helps to improve the appearance of scars while preventing new scar tissue and hyperpigmentation caused by UV exposure.

Warnings:
For External use only
Keep out of reach of children
Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs.

Directions:
• Wash and dry affected area.
• Apply every twice daily, 15 minutes before sun exposure, to affected area and gently massage. Allow to dry.
• Reapplication is recommended after swimming or sweating.
• Children under 6 months of age. Ask a doctor.

Other Information
Store between 15°C (59°F) and 27°C (80°F). Protect product in its container from excessive heat and direct sun.

Inactive Ingredients
Polymerized Silicones, Silicone Gel, C12-15 Alkyl Benzoates, Polyhydroxyacetic Acid.

Questions? 1-888-638-6331 (3884)

Made in U.S.A. by
NewMedical Technology, Inc.
Northbrook, IL 60062 U.S.A.
www.silagen.com

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Instrucciones en Español:

"Silagen® Silicone Gel + SPF 30" está hecho con el gel de silicon grado medico de la mas alta calidad y con protección solar de minerales sin químicos. Este gel hipolergénico de silicona ayuda a suavizar, suavizar y mejorar la textura de cicatrices. Al mismo tiempo reduce enrojecimiento y previene la hiperpigmentación causada por los rayos ultravioleta (UV).

Modo de empleo:

Lave y seque el área afectada. Aplicar una pequeña cantidad de Silagen® Silicone Gel + SPF 30 en la cicatriz dos veces al día y 30 minutos antes de la exposición al sol y masajear suavemente. Lea el folleto para más detalles.

silagen®
SCAR REFINEMENT SYSTEM

**SILICONE GEL
FOR SCARS
+ SPF 30
UV PROTECTION**

5 1/4

net wt 30g



MKL075 V1

Silagen® Silicone Gel + SPF 30 is the first scar treatment to combine medical grade silicones with chemical-free mineral sunscreen. This fast drying gel will help flatten and smooth scars while reducing redness and itch.

The added UV protection helps to prevent permanent hyperpigmentation of fragile new scar tissue that can occur even with incidental sun exposure. Silagen®'s non-irritating, chemical-free sunscreen is a safer option because it remains on the surface of the skin and is not absorbed into the skin.

Silagen® Silicone Gel + SPF 30 can be used exclusively for the full course of treatment or alternated with other products in the Silagen® Scar Refinement System, including Silagen® Silicone Gel Sheeting.

Do not use Silagen® Silicone Gel + SPF 30 under Silagen® Silicone Gel Sheeting or it will cause the Sheeting to lose adhesiveness. Use Silagen® Silicone Gel + SPF 30 during the day and alternate with the Sheeting at night if desired.

10 11/16

8 15/32

Drug Facts	
Active Ingredients	
Purpose	
Zinc Oxide 20%.....	Sunscreen
Use	
Silagen® Silicone Gel + SPF 30 helps to improve the appearance of scars while preventing sunburn and hyperpigmentation caused by UV exposure.	
Warnings	
For External use only	
Keep out of reach of children	
Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs.	
Directions	
<ul style="list-style-type: none"> • Wash and dry affected area. • Apply evenly twice daily, 15 minutes before sun exposure, to affected area and gently massage. Allow to dry. • Reapplication is recommended after swimming or sweating. • Children under 6 months of age: Ask a doctor. 	
Other Information	
Store between 15°C (59°F) and 27°C (80°F). Protect product in this container from excessive heat and direct sun.	
Inactive Ingredients	
Polymerized Siloxanes (Silicone Gel), C12-15 Alkyl Benzoate, Polyhydroxystearic Acid	

NEWGEL PLUS SPF

zinc oxide, sunscreen gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69291-0850
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69291-0850-1	1 in 1 CARTON	08/01/2016	
1	NDC:69291-0850-2	15 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/01/2016	

Labeler - Newmedical Technology, Inc. (787828669)**Registrant** - Newmedical Technology, Inc. (787828669)**Establishment**

Name	Address	ID/FEI	Business Operations
Newmedical Technology, Inc.		787828669	manufacture(69291-0850)

Revised: 11/2017

Newmedical Technology, Inc.