

SILAGEN- 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

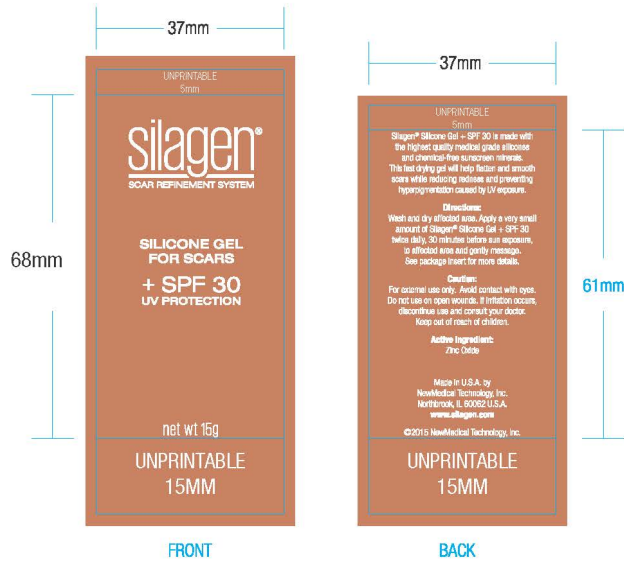
Zinc Oxide 20%.....Sunscreen



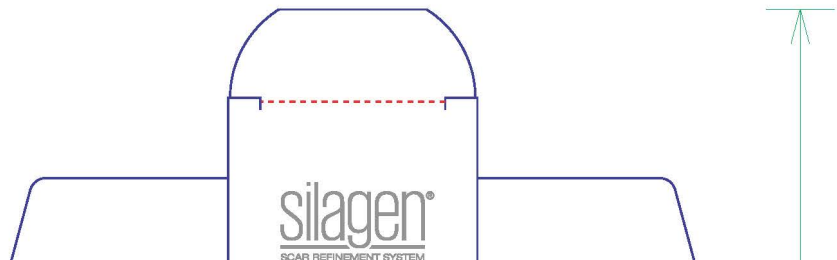
RT-15 Printing area

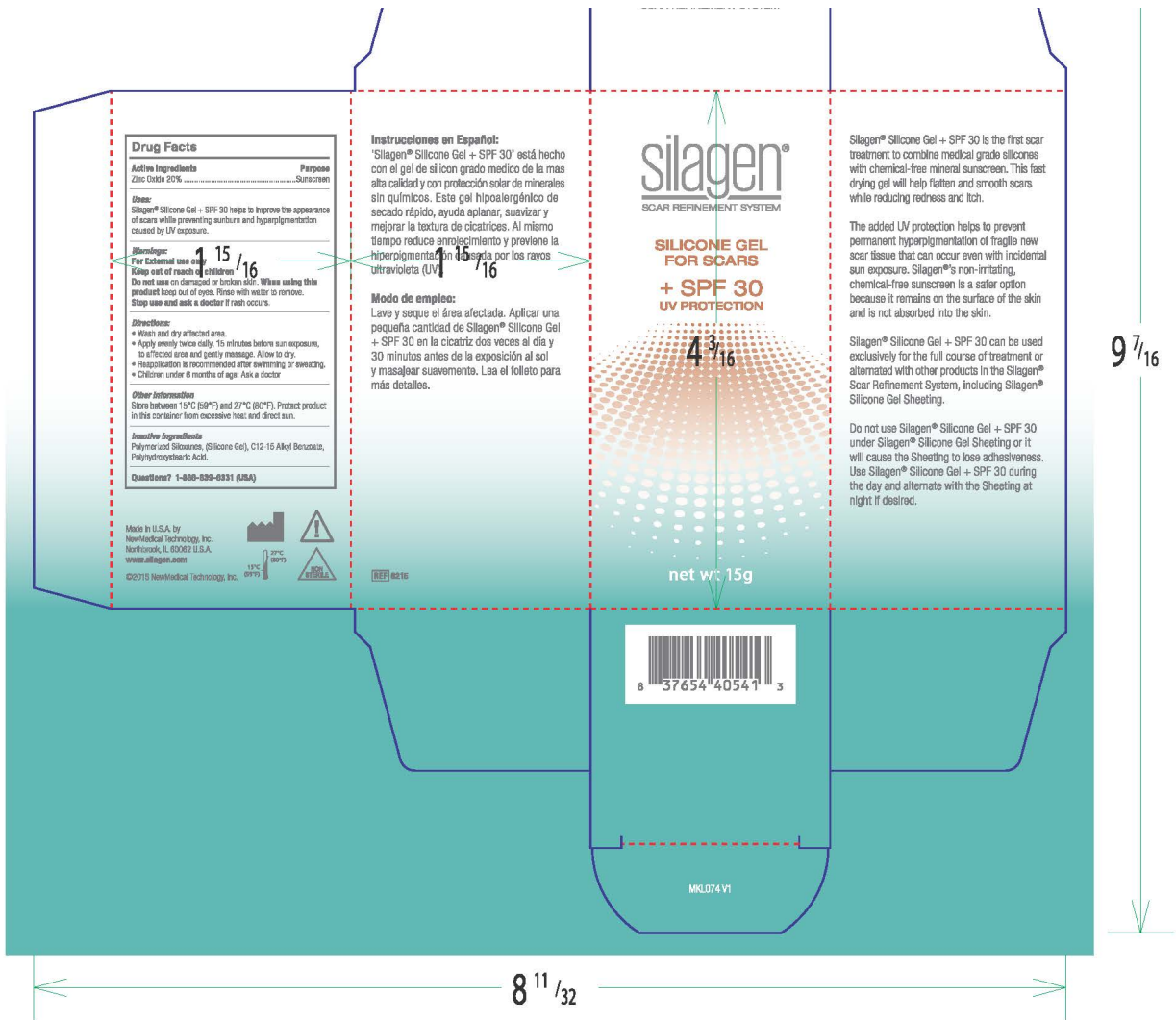
INNER WALL
LOGO + COPY
COLLAR/ACTUATOR

PMS 7591C
WHITE
SILVER METALLIZATION



SILAGEN UV UNIT CARTON 15 G





Drug Facts

Active Ingredients Purpose
Zinc Oxide 20% Sunscreen

Uses: 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:
• 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 8 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: Polyvinyl Siloxane, (Silicone Gel), C12-15 Alkyl Benzoate, Polyhydroxyethyl Acid.

Questions? 1-888-698-6331 (USA)

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



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 hiperalérgico de secado rápido, ayuda aplanar, suavizar y mejorar la textura de cicatrices. Al mismo tiempo reduce enrojecimiento y previene la hiperpigmentación 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

4 3/16

net wt. 15g



MKL074 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.

9 7/16

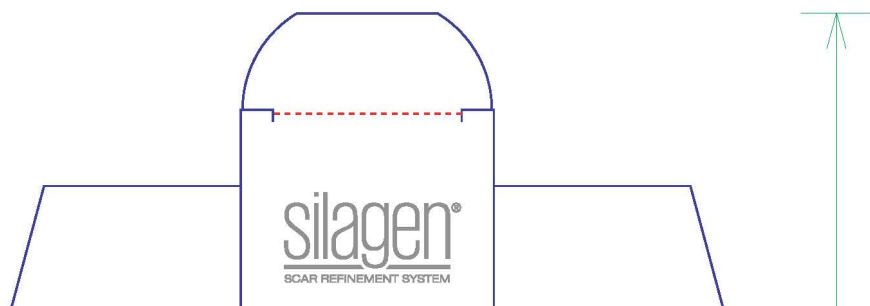
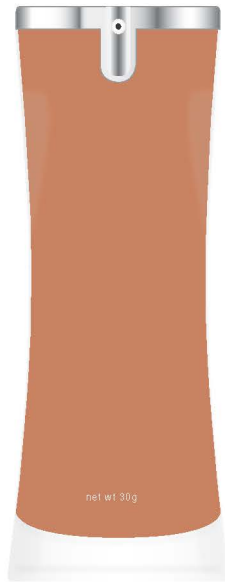
8 11/32



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 redness 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 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:
 Polymeric Silicones, (Silicone Gel), C12-15 Alkyl Benzoate, Polyhydroxyacid.

Questions? 1-800-838-8331 (USA)

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

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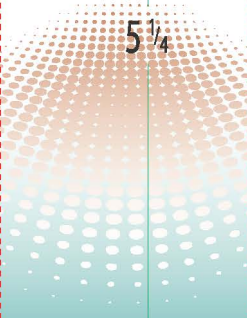
Instrucciones en Español:

'Silagen® Silicone Gel + SPF 30' está hecho con el gel de silicon grado médico de la más alta calidad y con protección solar de minerales sin químicos. Este gel hiperalérgico de secado rápido ayuda a alisar, 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**



net wt 30g

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.



MKL075 V1

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	

SILAGEN

zinc oxide, sunscreen gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69291-6215
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 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69291-6215-1	1 in 1 CARTON	06/01/2015	
1	NDC:69291-6215-2	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	06/01/2015	

SILAGEN

zinc oxide, sunscreen gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69291-6230
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
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	

DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69291-6230-1	1 in 1 CARTON	06/01/2015	
1	NDC:69291-6230-2	30 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	06/01/2015	

Labeler - NewMedical Technology Inc. (787828669)

Registrant - NewMedical Technology Inc. (787828669)

Establishment

Name	Address	ID/FEI	Business Operations
NewMedical Technology Inc.		787828669	manufacture(69291-6215, 69291-6230)

Revised: 6/2023

NewMedical Technology Inc.