NEWGEL PLUS SPF- zinc oxide, sunscreen gel
BRUISE MD- allantoin 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

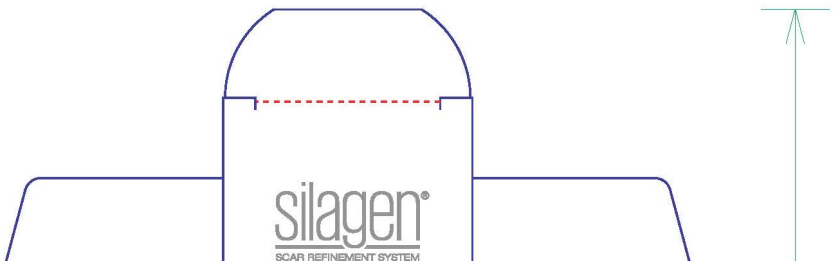
PMS 7591C | WHITE | SILVER METALLIZATION

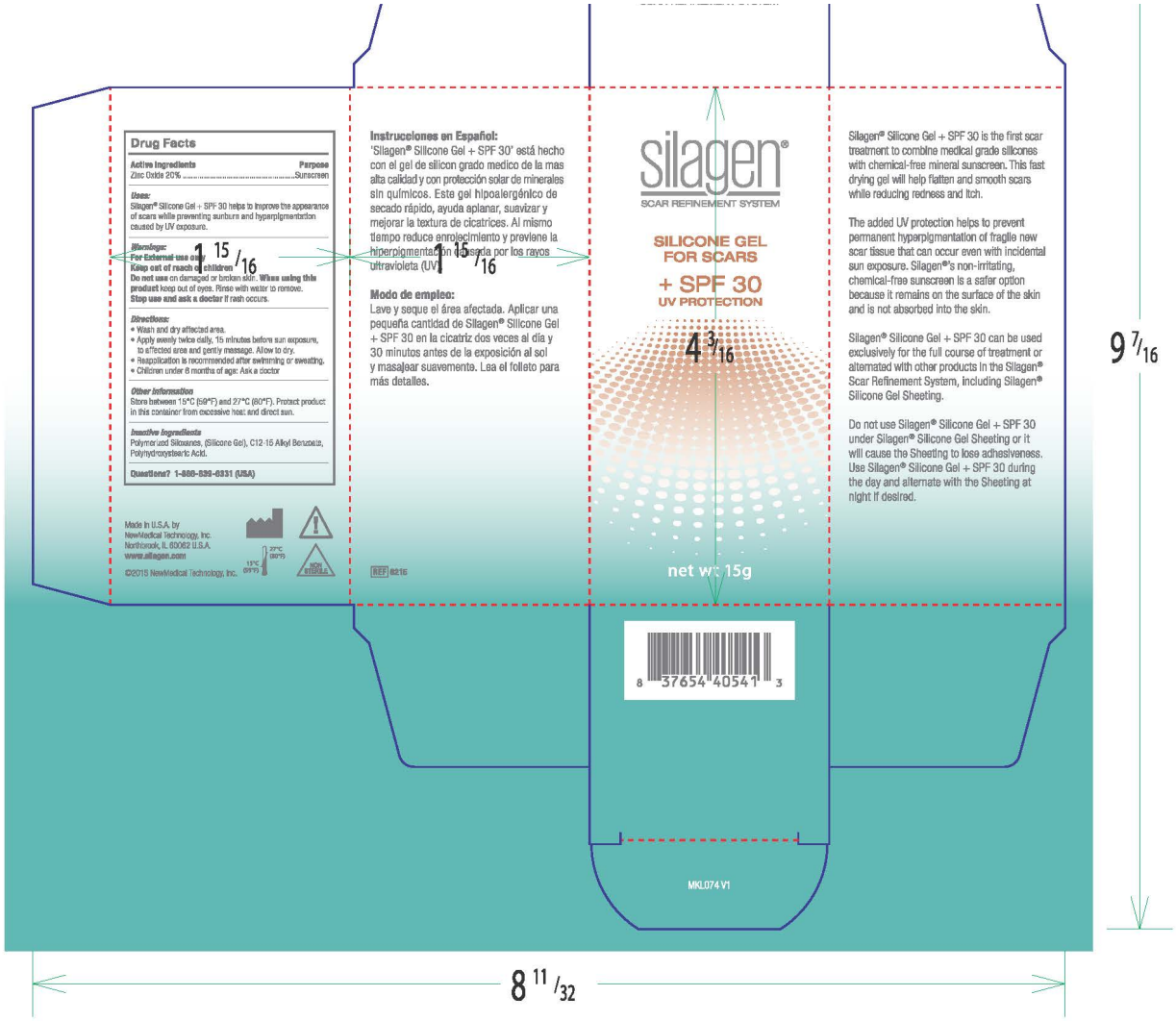
RT-15 Printing area

INNER WALL	PMS 7591C
LOGO + COPY	WHITE
COLLAR/ACTUATOR	SILVER METALLIZATION

SILAGEN UV UNIT CARTON 15 G 04.17.15

PMS 7591C | PMS 7472C | PMS COOL GRAY 9C | PMS 877C

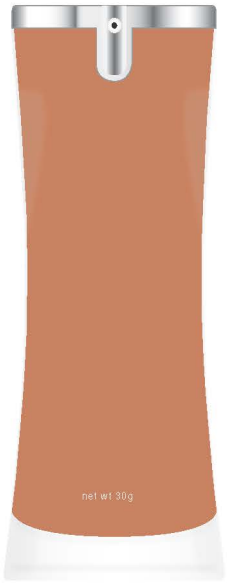


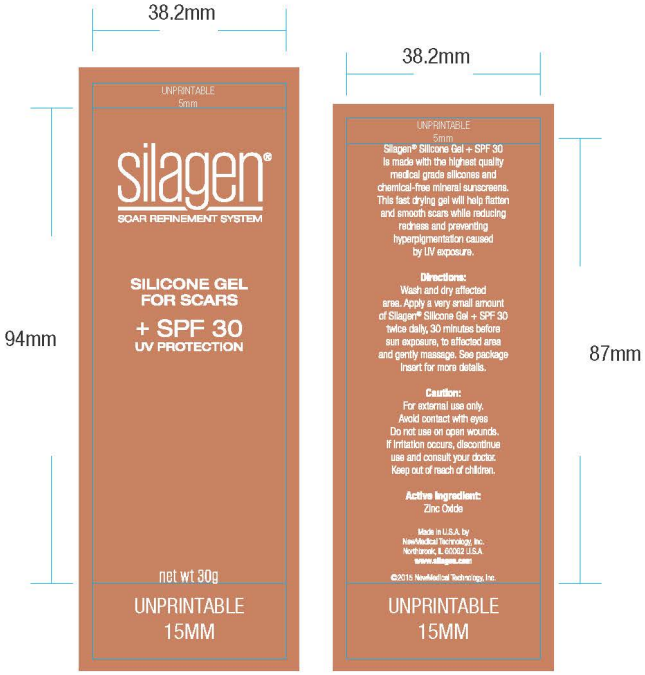

Drug Facts
Active Ingredients
Zinc Oxide 20%
Purpose
Sunscreen
Uses:
Silagen® Silicone Gel + SPF 30 helps to improve the appearance of scars while preventing sunburn and hyperpigmentation caused by UV exposure.
Warnings:
For External use only
Keep out of reach of children
Do not use on damaged or broken 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 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.
Questions? 1-888-538-6331 (USA)
Made in U.S.A. by
NewMedical Technology, Inc.
Northbrook, IL 60062 U.S.A.
www.silagen.com
©2015 NewMedical Technology, Inc.
27°C (80°F)
15°C (59°F)
NON STERILE
1 15/16
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 hipoalergénico de secado rápido, ayuda aplanar, 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.
REF 6215
1 15/16
silagen®
SCAR REFINEMENT SYSTEM
SILICONE GEL FOR SCARS
+ SPF 30
UV PROTECTION
4 3/16
net wt. 15g
8 37654 40541 3
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

PMS 7591C | WHITE | SILVER METALLIZATION

RT-30 Printing area

INNER WALL	PMS 7591C
LOGO + COPY	WHITE
COLLAR/ACTUATOR	SILVER METALLIZATION

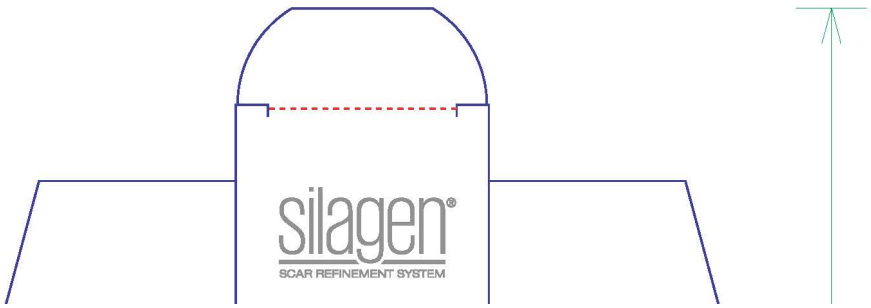


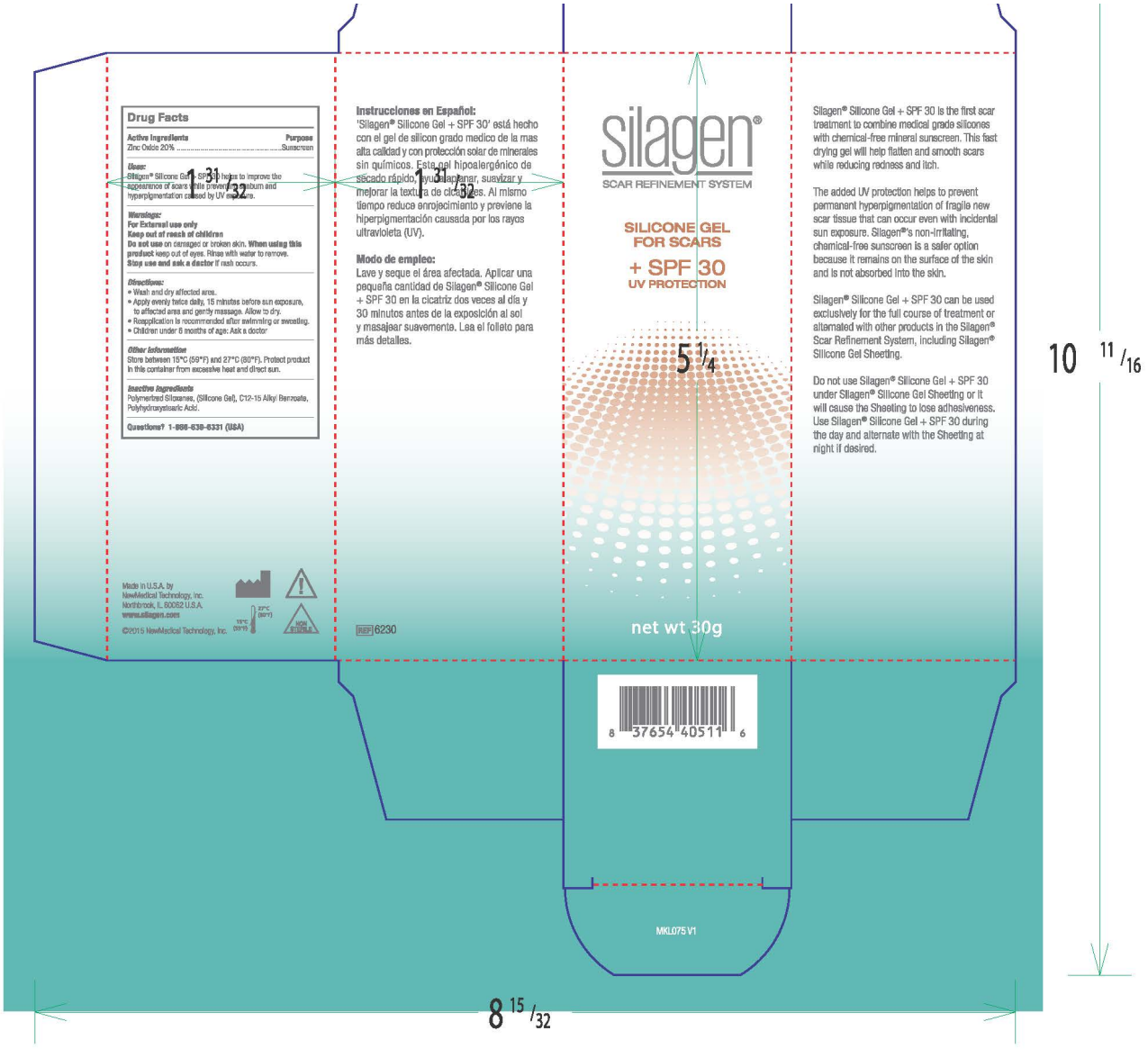


FRONT BACK

SILAGEN UV UNIT CARTON 30 G 04.17.15

PMS 7591C | PMS 7472C | PMS COOL GRAY 9C | PMS 877C




Drug Facts
Active Ingredients
Zinc Oxide 20%
Purpose
Sunscreen
Uses:
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Other Information
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Questions? 1-866-638-8331 (USA)
1 31/32
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1 31/32
silagen®
SCAR REFINEMENT SYSTEM
SILICONE GEL FOR SCARS
+ SPF 30
UV PROTECTION
5 1/4
net wt 30g
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10 11/16
Made in U.S.A. by
NewMedical Technology, Inc.
Northbrook, IL 60062 U.S.A.
www.silagen.com
©2015 NewMedical Technology, Inc.
15°C (59°F)
27°C (80°F)
NON STERILE
REF 6230
8 37654 40511 6
MKL075 V1
8 15/32

Drug Facts

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

Use
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NEWGEL PLUS SPF
zinc oxide, sunscreen gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69291-8050
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)	
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:69291-8050-2	15 g in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	10/03/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/01/2016	

BRUISE MD

allantoin gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69291-9020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.55 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BROMELAINS (UNII: U182GP2CF3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

ASCORBIC ACID (UNII: PQ6CK8PD0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLUCOSYL HESPERIDIN (UNII: 432C95B6YE)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA (UNII: O80TY208ZW)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
.ALPHA.N-(METHOXYCARBONYL)-L-ARGININE (UNII: PE4EFA9P6E)	
PHYTONADIONE (UNII: A034SE7857)	
NIACINAMIDE (UNII: 25X51I8RD4)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69291-9020-1	1 in 1 CARTON	12/02/2019	
1	NDC:69291-9020-2	20 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
OTC monograph final	part347	01/20/2019	

Labeler - Newmedical Technology, Inc. (787828669)

Registrant - Newmedical Technology, Inc. (787828669)

Establishment

Name	Address	ID/FEI	Business Operations
Newmedical Technology, Inc.		787828669	manufacture(69291-8050, 69291-9020)

Revised: 6/2023 Newmedical Technology, Inc.