PRO-SIL SPF- silicone stick with spf stick Biodermis, LLC

ProSil SPF

DESCRIPTION:

PROSIL SPF15
SILICONE STICK FOR SCARS
GLIDE-ON THERAPY FOR YOUR SCARS

ACTIVE INGREDIENTS:

Avobenzone - 3% Sunscreen

Octocrylene - 5% Sunscreen agent

Octinoxate - 4% Sunscreen agent

DOSAGE & ADMINISTRATION:

Apply 15 minutes before sun exposure. Clean and dry scar site before each application. Apply Pro-Sil® liberally over the entire scar. May be covered with a bandage. Repeat several times daily for 8-12 weeks or until scar stops responding. To remove, wipe off with a clean cloth or tissue.

PURPOSE:

SILICONE STICK FOR SCARS
BROAD SPECTRUM UVA/UVB SUNSCREEN
HELPS PREVENT SUNBURN

INDICATIONS & USAGE:

SILICONE STICK FOR SCARS
BROAD SPECTRUM UVA/UVB SUNSCREEN
HELPS PREVENT SUNBURN

DIRECTIONS:

Apply 15 minutes before sun exposure. Clean and dry scar site before each application. Apply Pro-Sil® liberally over the entire scar. May be covered with a bandage. Repeat several times daily for 8–12 weeks or until scar stops responding. To remove, wipe off with a clean cloth or tissue. Store

between 55°F-95°F (13°C-35°C).

WARNINGS:

FOR EXTERNAL USE ONLY

WARNINGS AND PRECAUTIONS:

EXTERNAL USE ONLY

CAUTIONS: Stop use and ask a doctor if rash occurs. Do not use on damaged or broken skin. For children under 5 year of age, use under adult supervision. Children under 6 months of age: Ask a doctor.

CAUTIONS:

Stop use and ask a doctor if rash occurs. Do not use on damaged or broken skin. For children under 5 year of age, use under adult supervision. Children under 6 months of age: Ask a doctor.

KEEP OUT OF REACH OF CHILDREN:

KEEP OUT OF REACH OF CHILDREN:

ASK A DOCTOR:

Ask a doctor about using PROSIL SPF with children under 6 months old.

STORAGE:

Store between 55°F-95°F (13°C-35°C).

CONTACT INFORMATION:

MADE IN THE USA U.S. Patent No. 8,557,287

BIODERMIS LLC 1820 Whitney Mesa Drive, Suite 100

Henderson, Nevada 89014 USA

800.322.3729 (USA) 702.260.4466 (INTL)

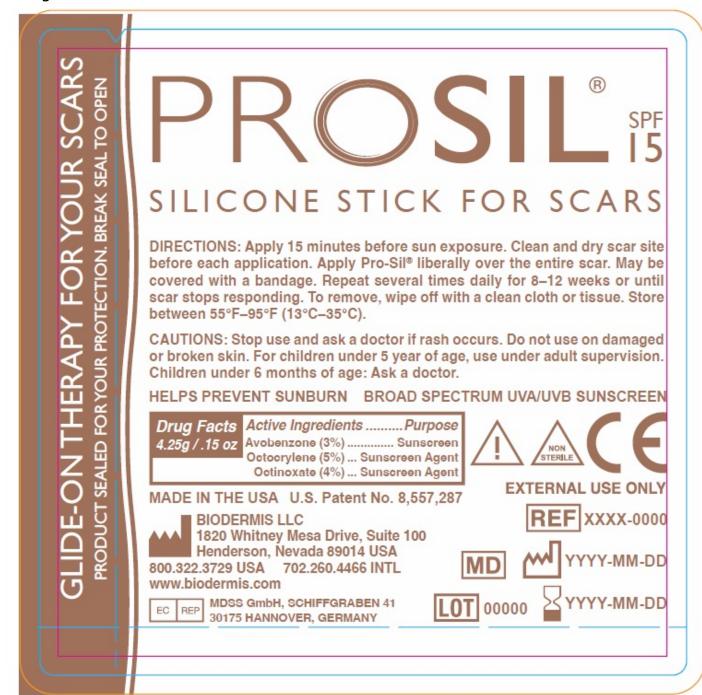
www.biodermis.com

INACTIVE INGREDIENTS:

Silicone

Primary Package Label

4.25g Tube:



17g Tube:

GLIDE-ON THERAPY FOR YOUR SCARS
RODUCT SEALED FOR YOUR PROTECTION, BREAK SEAL TO OPEN

SPF

SILICONE STICK FOR SCARS

DIRECTIONS: Apply 15 minutes before sun exposure. Clean and dry scar site before each application. Apply Pro-Sil® liberally over the entire scar. May be covered with a bandage. Repeat several times daily for 8-12 weeks or until scar stops responding. To remove, wipe off with a clean cloth or tissue. Store between 55°F-95°F (13°C-35°C).

CAUTIONS: Stop use and ask a doctor if rash occurs. Do not use on damaged or broken skin. For children under 5 year of age, use under adult supervision. Children under 6 months of age: Ask a doctor.

BROAD SPECTRUM UVA/UVB SUNSCREEN HELPS PREVENT SUNBURN U.S. Patent No. 8,557,287 MADE IN THE USA EXTERNAL USE ONLY

17g / .60 oz

Drug Facts Active Ingredients Purpose Avobenzone (3%)...... Sunscreen Octocrylene (5%)... Sunscreen Agent Octinoxate (4%)... Sunscreen Agent

BIODERMIS LLC 1820 Whitney Mesa Drive, Suite 100 Henderson, Nevada 89014 USA

Y-MM-DD MD

800.322.3729 USA 702.260.4466 INTL www.blodermls.com

MDSS GmbH, SCHIFFGRABEN 41 30175 HANNOVER, GERMANY





REF XXXX-0000

REV: G

DWG: 6085

1g Sample Tube:

tamper seal



PRO-SIL SPF

silicone stick with spf stick

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:84440-608

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	40 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SILICON (UNII: Z4152N8IUI)	880 mg in 1 g

			in	

	ackaging						
4	tem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:84440- 608-01	1 g in 1 TUBE; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug	08/08/2025				
	NDC:84440-	4.25 g in 1 TUBE; Type 4: Device	N9/N9/2N25				

0	TC Monograph	Drug	M020	08/08/2025	
Marketing Category		_	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Marketing Information					
3	NDC:84440- 608-17		n 1 TUBE; Type 4: Device d/Impregnated/Otherwise Combined with Drug	08/08/2025	
	608-42	Coated	d/Impregnated/Otherwise Combined with Drug	00/00/2025	

Labeler - Biodermis, LLC (809650005)

Revised: 8/2025 Biodermis, LLC