SCARSCREEN- zinc oxide lotion
Natural Crest Laboratories 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.

ScarScreen

Drug Facts

Active Ingredient

Zinc Oxide 15%

Purpose

Sunscreen

Keep out of reach of children.

Uses

Helps prevent sunburn.

Warnings

When Using This Product

- If product gets into eyes, rinse thoroughly with water
- If irritation or stinging occurs, wash area with water

For external use only.

If swallowed, get medical help right away.

Do not use on damaged or broken skin.

Stop use and ask doctor if rash occurs.

Directions

Shake Well

Adults and children 6 months of age and over	Apply liberally and evenly to skin area 15 minutes before you are exposed to sun or water. Reapply at least every two hours. Use a water-resistant sunscreen if swimming or sweating.”
Children under 6 months of	Ask a doctor

age	

Consult a physician for use on children under 6 months.

Inactive ingredients

C12-C15 alkyl benzoic acid, Cetearyl alcohol and ceteareth-20, Citric acid, Corn starch, Dimethicone, Ethylhexyl glycerin, Glyceryl stearate, Isostearic acid, Methyl gluceth-10, Methylcellulose, PEG-40 stearate, Polyhydroxystearic acid, Phenoxyethanol, Propylene glycol, SDA 40B alcohol, Xanthan gum, Water

SPF 30

broad spectrum sunscreen

formulated for scars

perfect protection for scars' sensitive skin

UVA/UVB protection

A Sunscreen Especially for Scars. From the Scar Experts at Dermaflage.

Scar tissue is fragile and particularly susceptible to the harmful rays of the sun. That's why we developed ScarScreen, the perfect protection for scars' sensitive skin. Ideal for use following cosmetic procedures, Doctors recommend sun protection for minimizing a scar and preventing hyperpigmentation. Conceal and protect your scar-ScarScreen is specially formulated to work with Dermaflage Topical Filler.

* No synthetic chemical sunscreen

* Hypoallergenic

* Ideal for use after surgery

* Fragrance free

* Specially formulated to work with Dermaflage Topical Filler

Made in the U.S.A.

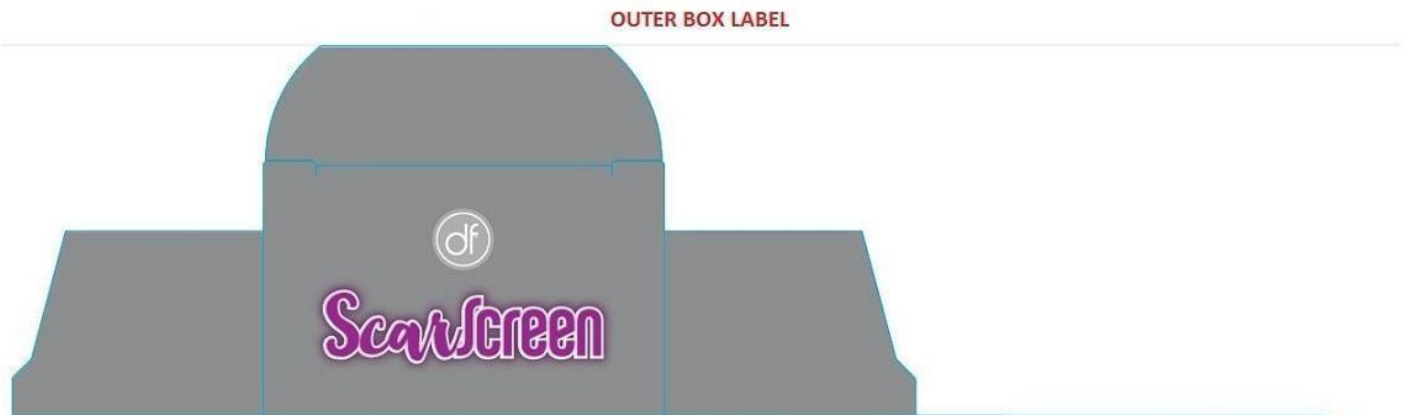
Distributed by

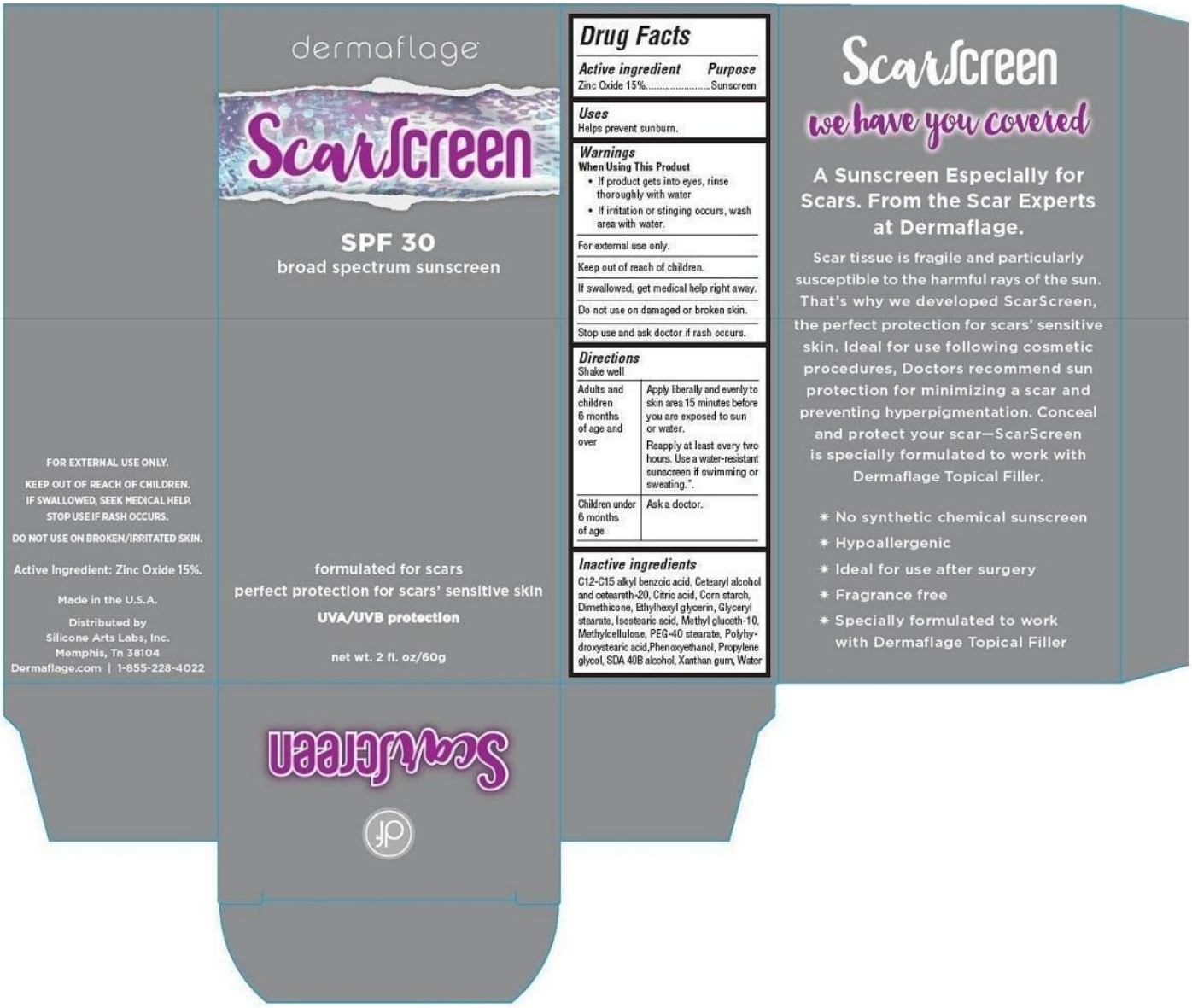
Silicone Arts Labs, Inc.

Memphis, Tn 38104

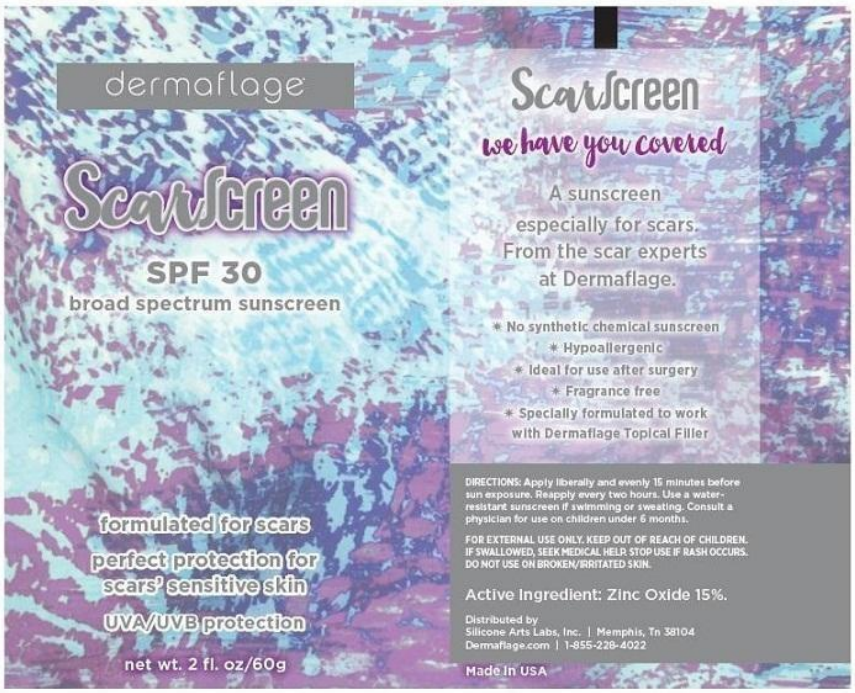
Dermaflage.com | 1-855-228-4022

Packaging





INNER TUBE LABEL



SCARSCREEN

zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70089-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.75 g in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
STARCH, CORN (UNII: O8232NY3SJ)	
DIMETHICONE 200 (UNII: RGS4T2AS00)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
METHYL GLUCETH-10 (UNII: N0MWT4C7WH)	
METHYLCELLULOSE (4000 MPA.S) (UNII: MRJ667KA5E)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALCOHOL (UNII: 3K9958V90M)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70089-100-11	1 in 1 BOX	09/15/2015	
1	NDC:70089-100-10	60 mL 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 not final	part352	09/15/2015	

Labeler - Natural Crest Laboratories Inc. (050926699)

Establishment

Name	Address	ID/FEI	Business Operations
Natural Crest Laboratories Inc.		050926699	manufacture(70089-100)

Revised: 9/2015 Natural Crest Laboratories Inc.