SUN NATURAL SUNSCREEN- zinc oxide cream Sun Naturals 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.

Sun Natural Sunscreen

Drug Facts

Active ingredient

Zinc Oxide 22%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

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

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure
- Reapply:
- After 80 minutes of swimming or sweating
- Immediately after towel drying
- At least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
- Limit time in the sun, especially from 10 a.m. -2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses

• Children under 6 months of age: Ask a doctor

Other information

• Protect the product in this container from excessive heat and direct sun

Inactive ingredients

Caprylic/Capric Triglyceride, Grape (Vitis vinifera) Seed Oil, Silica, Shea (Butyrospermum parkii) Butter, Candelilla (Euphorbia cerifera) Wax, Beeswax, Fragrance (Parfum), Jojoba (Simmondsia chinensis) Seed Oil, Tocopherol, Safflower (Carthamus tinctorius) Seed Oil, Cucumber (Cucumis sativus) Fruit Extract, Glycerin, Water (Aqua), Tea (Camellia sinensis) Leaf Extract, Rosehip (Rosa canina) Fruit Oil

Package Labeling:

WE LOVE THE SUN.

We Just Want You And Your Family To Be Covered.

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Sun Naturals Inc, Fremantle, Western Australia 6158

NDC# 71086-000-01 100% Made in Australia.







To Report A Serious Adverse Event Contact 1-604-908-1918. Expiration Date: www.naturalsunscreen.com



SUN NATURAL SUNSCREEN

zinc oxide cream

Product Information Product Type HUMAN OTC DRUG Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

NDC:71086-000

Inactive Ingredients			
Ingredient Name	Strength		
SHEA BUTTER (UNII: K49 155WL9 Y)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
CANDELILLA WAX (UNII: WL0328 HX19)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
JOJOBA OIL (UNII: 724GKU717M)			
TOCOPHEROL (UNII: R0ZB2556P8)			
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			
TEA LEAF (UNII: GH42T47V24)			
ROSA CANINA FRUIT (UNII: 3TNW8D08V3)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
GRAPE SEED OIL (UNII: 930 MLC8 XGG)			

I	Packaging	ackaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
	NDC:71086-000-01	1 in 1 BOX	11/16/2016				
	1	100 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 not final	part352	11/16/2016			

Labeler - Sun Naturals Inc (259934094)

Revised: 11/2016 Sun Naturals Inc