

# **DERMATONE SPF 50 SUNSCREEN STICK- zinc oxide stick**

## **Dermatone**

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### **Drug Facts**

#### **Active ingredient**

Zinc Oxide...20.0%

#### **Purpose**

Sunscreen

#### **Keep Out of Reach of Children**

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

#### **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.

#### **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 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-sleeve shirts, pants, hats and sunglasses. Children under 6 months: Ask a doctor.

#### **Inactive Ingredients**

Aloe Extract, Behenyl Behenate, Shea Butter, Caprylic/Capric Triglyceride, Coconut Oil, Candelilla Wax, Sunflower Oil, Sunflower Wax, Polyhydroxystearic Acid, Castor Oil, Jojoba Oil, Squalane, Cocoa Butter, Tocopherol (Vitamin E).

#### **Package/Label Principal Display Panel**

LAB-2581

**Drug Facts**

Active ingredients	Purpose
Zinc Oxide (20.0%)	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:**

**Skin Cancer / Skin Aging Alert:**  
Spending time in the sun increases your risk of skin cancer and early skin aging.

**For external use only.**



MADE IN THE USA With US and Imported Materials  
Distributed by Dermatone Labs, LLC  
Southport, CT 06890



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**Drug Facts (continued)**

**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 product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions:**  
Apply liberally 15 minutes before sun exposure. Reapply:

- After 80 min. of swimming or sweating
- Immediately after towel drying
- At least every 2 hours

**Sun Protection Measures:**  
Use a sunscreen with a broad spectrum SPF 15 or higher and other sun protection measures:

- Limit time in sun, especially from 10am to 2 pm
- Wear long sleeve shirts, pants, hats and sunglasses
- Children under 6 months: Ask a doctor

**Drug Facts (continued)**

**Inactive ingredients:**  
Cocos Nucifera (Coconut) Oil, Behenyl Behenate, Helianthus Annuus (Sunflower) Seed Oil, Theobroma Cacao (Cocoa) Seed Butter, Polyhydroxystearic Acid, Ricinus Communis (Castor) Seed Oil, Squalane, Helianthus Annuus (Sunflower) Seed Wax, Butyrospermum Parkii (Shea Butter), Euphorbia Cerifera (Candelilla) Wax, Tocopherol, Caprylic/Capric Triglyceride, Simmondsia Chinensis (Jojoba) Seed Oil, Aloe Barbadensis Leaf Extract.

**Other information**  
Protect this product from excessive heat and direct sun.

**Questions? 203-858-2663**

## DERMATONE SPF 50 SUNSCREEN STICK

zinc oxide stick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54414-108
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
COCONUT OIL (UNII: Q9L0O73W7L)	395 mg in 1 g
WHITE WAX (UNII: 7G1J5DA97F)	162 mg in 1 g
COCOA BUTTER (UNII: 512OYT1CRR)	57 mg in 1 g
SUNFLOWER OIL (UNII: 3W1JG795YI)	64 mg in 1 g

### Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	

Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54414-108-01	14 g in 1 CONTAINER; Type 0: Not a Combination Product	12/16/2025	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		352	12/16/2025	

**Labeler** - Dermatone (100928460)

**Registrant** - OraLabs (801824756)

Establishment			
Name	Address	ID/FEI	Business Operations
OraLabs		801824756	manufacture(54414-108) , label(54414-108) , analysis(54414-108)

Revised: 12/2025 Dermatone