SPF 30 - ZINC OXIDE LIP BALM- zinc oxide stick Dermatone

Drug Facts

Active ingredient

Zinc Oxide (15.0%)

Purpose

Sunscreen

Keep Out of Reach of Children

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

Uses

Prevents Sunburns

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown to prevent sunburn, skin cancer and/or early aging.

For external use only: Stop use and ask a doctor: if rash or irritation develops and lasts.

Directions

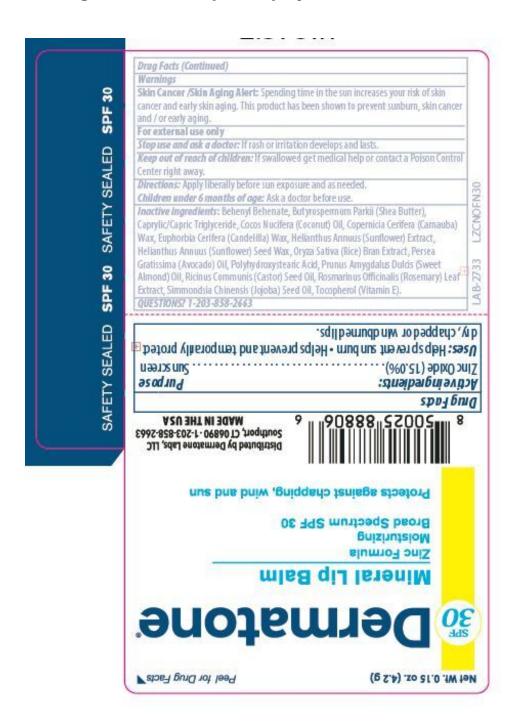
Apply liberally 15 minutes before sun exposure • reapply: after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging • To decrease the risk, regularly use a sunscreen with a broad spectrum SPF 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

Behenyl Behenate, Butyrospermum Parkii (Shea Butter), Caprylic/Capric Triglyceride, Cocos Nucifera (Coconut) Oil, Copernicia Cerifera (Carnauba) Wax, Euphorbia Cerifera

(Candelilla) Wax, Helianthus Annuus (Sunflower) Extract, Helianthus Annuus (Sunflower) Seed Wax, Oryza Sativa (Rice) Bran Extract, Persea Gratissima (Avocado) Oil, Polyhydroxystearic Acid, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Ricinus Communis (Castor) Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract, Simmondsia Chinensis (Jojoba) Seed Oil, Tocopherol (Vitamin E).

Package/Label Principal Display Panel



SPF 30 - ZINC OXIDE LIP BALM

zinc oxide stick

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:54414-107

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH547) (ZINC OXIDE - UNII:SOI2LOH547)	ZINC OXIDE	150 ma in 1 a	

Inactive Ingredients

Ingredient Name	Strength	
COCONUT OIL (UNII: Q9L0O73W7L)	202 mg in 1 g	
WHITE WAX (UNII: 7G1J5DA97F)	182 mg in 1 g	
CASTOR OIL (UNII: D5340Y2I9G)	162 mg in 1 g	

Product Characteristics

Color	white	Score
Shape		Size
Flavor		Imprint Code
Contains		

Packaging

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	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:54414- 107-01	4.2 g in 1 CONTAINER; Type 0: Not a Combination Product	04/29/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	352	04/29/2025		

Labeler - Dermatone (100928460)

Registrant - OraLabs (801824756)

Establishment

Establishinent			
Name	Address	ID/FEI	Business Operations
OraLabs		801824756	manufacture(54414-107), label(54414-107), analysis(54414-107)

Revised: 12/2025 Dermatone