

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

Safety Sealed

SPF 30

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Peel for Drug Facts

Net Wt. 0.15 oz. (4.2 g)

SPF 30

Mineral Lip Balm

Zinc Formula

Moisturizing

Broad Spectrum SPF 30

Protects against chapping, wind and sun

Dermatone

Distributed by Dermatone Labs, LLC

Southport, CT 06890 • 1-203-858-2663

MADE IN THE USA

Drug Facts

Active Ingredients:

Zinc Oxide (15.0%).....Sun screen

Uses: Help prevent sun burn • Helps prevent and temporarily protect dry, chapped or windburned lips.

Drug Facts (Continued)

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.

Keep out of reach of children: If swallowed get medical help or contact a Poison Control Center right away.

Directions: Apply liberally before sun exposure and as needed.

Children under 6 months of age: Ask a doctor before use.

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).

QUESTIONS? 1-203-858-2663

SPF 30 - ZINC OXIDE LIP BALM

zinc oxide stick

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		TOPICAL	NDC:54414-107	
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)			ZINC OXIDE	150 mg in 1 g
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				
#	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

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