

SPF 30 - ZINC OXIDE LIP BALM- zinc oxide stick

OraLabs

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

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:63645-184
Route of Administration	TOPICAL		

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:63645-184-01	4 g in 1 CONTAINER; Type 0: Not a Combination Product	02/03/2025	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	352		02/03/2025	

Labeler - OraLabs (801824756)

Registrant - OraLabs (801824756)

Establishment			
Name	Address	ID/FEI	Business Operations
OraLabs		801824756	manufacture(63645-184) , label(63645-184) , analysis(63645-184)