SPF 15 - ZINC OXIDE LIP BALM- zinc oxide stick OraLabs

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.

Drug Facts

Active ingredient

Zinc Oxide (10.0%)

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

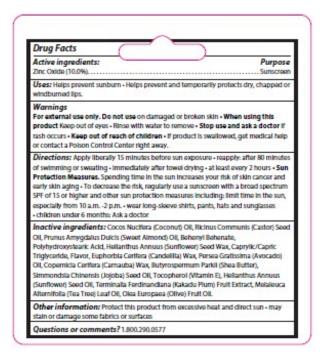
SPF of 15 or higher and other sun protection measures including: limit time in the sun,

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

Cocos Nucifera (Coconut) Oil, Ricinus Communis (Castor) Seed Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Behenyl Behenate, Polyhydroxystearic Acid, Helianthus Annuus (Sunflower) Seed Wax, Caprylic/CapricTriglyceride, Flavor, Euphorbia Cerifera (Candelilla) Wax, Persea Gratissima (Avocado) Oil, Copernicia Cerifera (Carnauba) Wax, Butyrospermum Parkii (Shea Butter),Simmondsia Chinensis (Jojoba) Seed Oil, Tocopherol (Vitamin E), Helianthus Annuus(Sunflower) Seed Oil, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Melaleuca

Package/Label Principal Display Panel



SPF 15 - ZINC OXIDE LIP BALM

zinc oxide stick

Product Information						
Product Type	HUMAN OTC DRUG Item Code (Source) NDC:63645-182			5-182		
Route of Administration	TOPICAL					
Active Ingredient/Active Moiety						
	inery					
Ingred	Basis of Stren	gth S	trength			
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)			ZINC OXIDE	100	mg in 1 g	
Inactive Ingredients						
Ingredient Name				Strength		

Packaging Marketing Start Marketing End # Item Code Package Description Marketing Start Marketing End 1 NDC:63645-182- 01 4 g in 1 CONTAINER; Type 0: Not a Combination Product 06/06/2023									
ALMOND OIL (UNII: 66YXD4DK09) 170 mg in 1 g CASTOR OIL (UNII: D5340Y2I9G) 170 mg in 1 g Product Characteristics 170 mg in 1 g Color WHITE Score Shape Size Imprint Code Flavor Imprint Code Contains Packaging Imprint Code Marketing Start Marketing Information 06/06/2023 Marketing Start Droduct Application Number or Monograph Citation Marketing Start Date Marketing Start Date Marketing Information Marketing Start Date DTC monograph not DTC mon	СС	DCONUT OIL (UNII:	: Q9L0O73W7L)			205 mg i	n 1 g		
CASTOR OIL (UNII: D5340Y219G) 170 mg in 1 g Product Characteristics Color WHITE Score Shape Size Flavor Imprint Code Contains Imprint Code Packaging # Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:63645-182- 4 g in 1 CONTAINER; Type 0: Not a Combination Of/06/2023 06/06/2023 Marketing Start Date Marketing End Date	W	HITE WAX (UNII: 70	G1J5DA97F)			202 mg i	n 1 g		
Product Characteristics Color WHITE Score Shape Size Shape Size Size Imprint Code Contains Packaging # Marketing Start Date Marketing Start Date Marketing Information Marketing Start Date Marketing Start Date Marketing Information Marketing Start Date Marketing Start Date Marketing Information Marketing Category Application Number or Monograph Marketing Start Date Marketing Start Date DTC monograph not nart352 06/06/2023	AL	MOND OIL (UNII: 6	66YXD4DKO9)			170 mg i	n 1 g		
Color WHITE Score Imprint Color Imprint Color Flavor Imprint Code Imprint Code Imprint Code Imprint Code Contains Imprint Code	CA	ASTOR OIL (UNII: D	5340Y2I9G)			170 mg i	n 1 g		
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			part352			06/06/2023			

Labeler - OraLabs (801824756)

Registrant - OraLabs (801824756)

Establishment								
Name	Address	ID/FEI	Business Operations					
OraLabs		801824756	MANUFACTURE(63645-182), LABEL(63645-182)					

Revised: 7/2023

OraLabs