

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

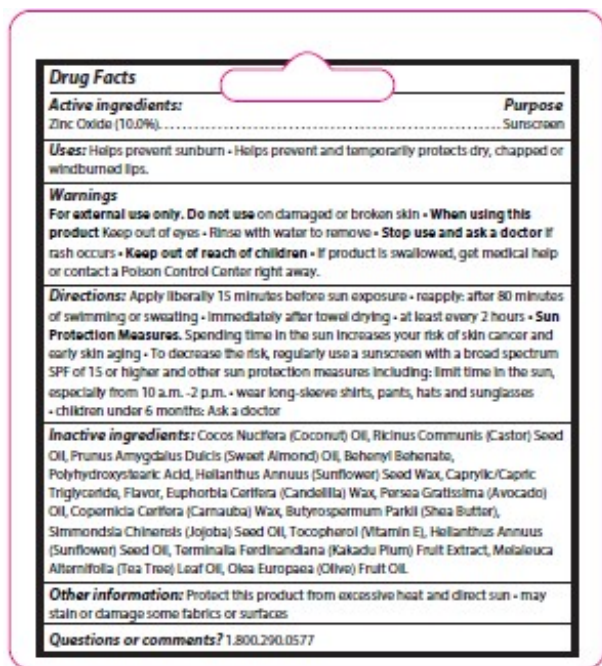
Apply liberally 15 minutes before sun exposure • reapply: after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • **Sun**

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/Capric Triglyceride, 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
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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COCONUT OIL (UNII: Q9L0O73W7L)	205 mg in 1 g
WHITE WAX (UNII: 7G1J5DA97F)	202 mg in 1 g
ALMOND OIL (UNII: 66YXD4DKO9)	170 mg in 1 g
CASTOR OIL (UNII: D5340Y2I9G)	170 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:63645-182-01	4 g in 1 CONTAINER; Type 0: Not a Combination Product	06/06/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	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

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