

**SPF 45 - LIP BALM- avobenzone, homosalate, octinoxate, octisalate,
petrolatum 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

Avobenzone 3.0%, Homosalate 3.0%, Octinoxate 7.5%, Octisalate 5.0%.....Sunscreen, Petrolatum 40.0%.....Skin Protectant

Purpose

Sunscreen, Skin Protectant

Keep Out of Reach of Children

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

Uses

Prevents Sunburns. Helps prevent wind burned and chapped lips.

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

C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Mineral Oil, Ozokerite, Phenyl Trimethicone, Tocopherol

Package/Label Principal Display Panel

DRUG FACTS	
Active Ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 3%	Sunscreen
Octinoxate 7.5%	Sunscreen
Octisalate 5%	Sunscreen
Petrolatum 40.0%	Skin Protectant
Uses: Helps prevent sunburn	
Warnings:	
<ul style="list-style-type: none"> • 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 only to help prevent sunburn, not skin cancer or early aging. • For external use only. • Do not use on damaged or broken skin. • Stop use and ask doctor if rash occurs. • When using this product keep out of eyes. Rinse with water to remove. • Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. 	
Directions:	
<ul style="list-style-type: none"> • Apply liberally 15 minutes before sun exposure • Reapply after 80 minutes of swimming or sweating • Reapply immediately after towel drying • Reapply at least every 2 hours • Children under 6 months: Ask a doctor 	
Inactive Ingredients: C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Flavor, Mineral Oil, Ozokerite, Phenyl Trimethicone, Saccharin, Tocopherol (Vitamin E).	
Other Information: Protect this product from excessive heat and direct sun.	

SPF 45 - LIP BALM

avobenzone, homosalate, octinoxate, octisalate, petrolatum stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63645-183
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	30 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	400 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	122 mg in 1 g
CERESIN (UNII: Q1LS2UJO3A)	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:63645-183-01	4 g in 1 CONTAINER; Type 0: Not a Combination Product	06/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2023	

Labeler - OraLabs (801824756)

Registrant - OraLabs (801824756)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(63645-183) , LABEL(63645-183)

Revised: 7/2023

OraLabs