

**CHAPICE SPF 30 LIP BALM- avobenzone, octisalate, homosalate,
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%), Octisalate (5.0%), Homosalate (8.0%)

Petrolatum (39.6%)

Purpose

Sunscreen, Sunscreen, Skin Protectant

Keep Out of Reach of Children

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

Uses

Helps prevent sunburn. if used as directed with other sun protection measures (see Directions) decreases the risk of skin cancer and early aging caused by the sun. helps prevent and temporarily protects chafed, chapped or cracked lips. Helps prevent and protect from the drying effects of wind and cold weather

Warnings

For external use only: Do not use on damaged or broken skin. When using this product. Keep out of eyes. Rinse with water to remove. Stop use and ask a doctor: if rash occurs

Directions

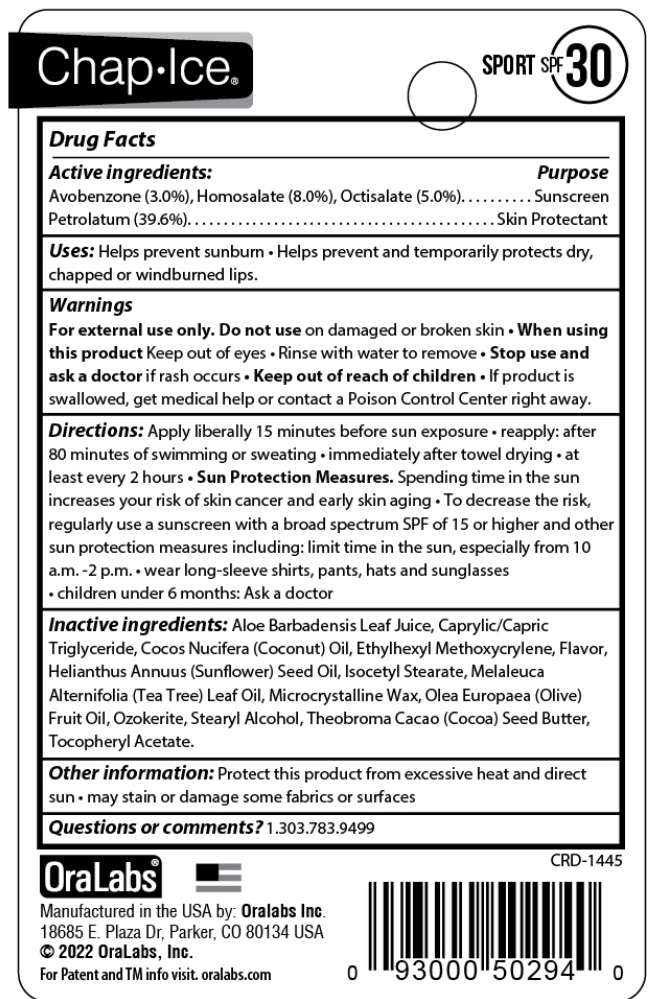
Apply liberally 15 minutes before sun exposure. Reapply: after 80 minutes of swimming or sweating. Immediately after towel drying. At least every 2 hours.

SunProtectionMeasures. 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. to 2 p.m. wear long-sleeve shirts, pants, hats and sunglasses. Children under 6 months: Ask a doctor.

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Beeswax, Caprylic/Capric Triglyceride, Cocos Nucifera (Coconut) Oil, Ethylhexyl Methoxycrylene, Flavor, Helianthus Annuus (Sunflower) Seed Oil, Isocetyl Stearate, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Microcrystalline Wax, Olea Europaea (Olive) Fruit Oil, Ozokerite, Stearyl Alcohol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate.

Package/Label Principal Display Panel



CHAPICE SPF 30 LIP BALM

avobenzone, octisalate, homosalate, petrolatum stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63645-180
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	396 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	80 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CERESIN (UNII: Q1LS2UJO3A)	165 mg in 1 g
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	23 mg in 1 g
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	5 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:63645-180-01	4.25 g in 1 CONTAINER; Type 0: Not a Combination Product	08/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2022	

Labeler - OraLabs (801824756)

Registrant - OraLabs (801824756)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(63645-180) , LABEL(63645-180)