

ORALABS CHAPICE ORIGINAL PETROLATUM- 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

Petrolatum, 45%

Purpose

Skin Protectant

Keep Out of Reach of Children

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

Uses

Helps prevent and temporarily protect dry, chapped or windburned lips.

Warnings

For external use only. Stop use and ask a doctor if rash or irritation develops and lasts. Children under 6 months of age: Ask a doctor before use.

Directions

Apply as needed.

Inactive Ingredients

Camphor, Cetyl Alcohol, Copernicia Cerifera (Carnauba) Wax, Euphorbia Cerifera (Candelilla) Wax, Flavor, Isopropyl Myristate, Lanolin, Microcrystalline Wax, Mineral Oil, Ozokerite, Phenyl Trimethicone, Red 6 Lake (CI 15850), Titanium Dioxide (CI 77891), Yellow 5 Lake (CI 19140).

Package/Label Principal Display Panel

SEALED
FOR YOUR
PROTECTION
Twist Cap
To Break Seal

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QUESTIONS? 1.800.290.0577

LAB-2465 LCS RGRYPG 00

Drug Facts

Active ingredients:	Purpose
Petrolatum (45.00%).....	Skin Protectant

Mfg. By: OraLabs, Inc.
18685 E. Plaza Dr. Parker, CO 80134



Chap•Ice®



Lip Balm
ORIGINAL



Chap•Ice®



Net Wt. 0.15 oz (4.25g)

▼Lift for Drug Facts Continued▼

ORALABS CHAPICE ORIGINAL PETROLATUM

petrolatum stick

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63645-169

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	45 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	28 ug in 1 g
WHITE WAX (UNII: 7G1J5DA97F)	17.5 mg in 1 g
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	3.0 mg in 1 g
LANOLIN (UNII: 7EV65EAW6H)	1.0 mg in 1 g

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63645-169-06	1 g in 1 CONTAINER; Type 0: Not a Combination Product	03/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/09/2020	

Labeler - OraLabs (801824756)

Registrant - OraLabs (801824756)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(63645-169) , LABEL(63645-169)