

ORALABS CHAPICE CHERRY 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

Drug Facts (Continued)
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Warnings
For external use only
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QUESTIONS? 1.800.290.0577

LAB-2466 LCS CCHYPIG 00

SEALED
FOR YOUR
PROTECTION
Twist Cap
To Break Seal

Drug Facts	Purpose
Active ingredients: Petrolatum (45.00%)	Skin Protectant

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



Lip Balm
CHERRY



Net Wt. 0.15 oz (4.25g)

▼Lift for Drug Facts Continued▼

ORALABS CHAPICE CHERRY PETROLATUM

petrolatum stick

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63645-170

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	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63645-170-06	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(63645-170) , LABEL(63645-170)