

## **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

SEALED  
FOR YOUR  
PROTECTION  
Twist Cap  
To Break Seal

**Drug Facts (Continued)**

**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.

**Keep out of reach of children:** if swallowed get medical help or contact a Poison Control Center right away.

**Directions:** Apply as needed.

**Children under 6 months of age:** Ask a doctor before use.

**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).

**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)

Revised: 3/2020

OraLabs