# SHOPKO MEDICATED LIP TREATMENT- camphor, phenol gel Shopko

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.

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## **Drug Facts**

# Active ingredient

Camphor (1.70%), Menthol (0.70%)

# Purpose

Analgesic, Anti-itch

# Keep Out of Reach of Children

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

#### Uses

For the temporary relief of pain and itching associated with fever blisters and cold sores. Helps prevent and temporarily protects dry chapped lips.

# Warnings

For external use only. When using this product: avoid contact with eyes. Rinse with water to remove. Stop use and ask a doctor if: rash or irritation develops and lasts for more than 7 days. Keep out of reach of children: if swallowed get medical help or contact a Poison Control Center right away.

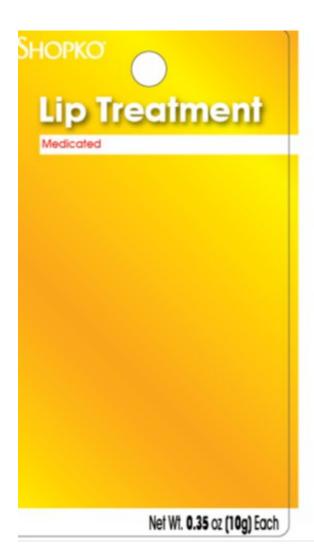
#### **Directions**

Apply liberally and evenly. Reapply as needed.

## **Inactive Ingredients**

Copernicia Cerifera (Carnauba) Wax, Flavor, Lanolin, Microcrystalline Wax, Mineral Oil, Ozokerite, Petrolatum, Phenol, Salicylic Acid, Theobroma Cacao (Cocoa) Seed Butter.

# Package/Label Principal Display Panel





## SHOPKO MEDICATED LIP TREATMENT

camphor, phenol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-735
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	1.700 mg in 1 g		
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	0.700 mg in 1 g		

Inactive Ingredients		
Ingredient Name	Strength	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	1.053 mg in 1 g	
PHENOL (UNII: 339 NCG44TV)	0.400 mg in 1 g	
EUCALYPTUS OIL (UNII: 2R04ONI662)	0.500 mg in 1 g	

<b>PETROLATUM</b> (UNII: 4T6 H12BN9 U) 83.947 mg in 1 g	
CERESIN (UNII: Q1LS2UJO3A)	1.000 mg in 1 g
LANOLIN (UNII: 7EV65EAW6H)	8.000 mg in 1 g

Product Characteristics		
Color	YELLOW	Score
Shape		Size
Flavor		Imprint Code
Contains		

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37012-735-04	1 g in 1 CONTAINER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/15/2013	

# **Labeler** - Shopko (023252638)

# Registrant - Shopko (023252638)

Establishment			
Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(37012-735), LABEL(37012-735)

Revised: 8/2013 Shopko