

## **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:370 12-735
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: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	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: 339NCG44TV)	0.400 mg in 1 g
EUCALYPTUS OIL (UNII: 2R04ONI662)	0.500 mg in 1 g

PETROLATUM (UNI: 4T6H12BN9U)	83.947 mg in 1 g
CERESIN (UNI: Q1LS2UJO3A)	1.000 mg in 1 g
LANOLIN (UNI: 7EV65EAW6H)	8.000 mg in 1 g

### Product Characteristics

Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:370 12-735-04	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(370 12-735) , LABEL(370 12-735)

Revised: 8/2013

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