

## **SHOPKO MEDICATED LIP BALM- petrolatum stick**

### **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**

Petrolatum

#### **Purpose**

Skin Protectant

#### **Keep Out of Reach of Children**

If swallowed, contact a Poison Control Center.

#### **Uses**

Helps prevent and temporarily protects chapped or windburned 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. .

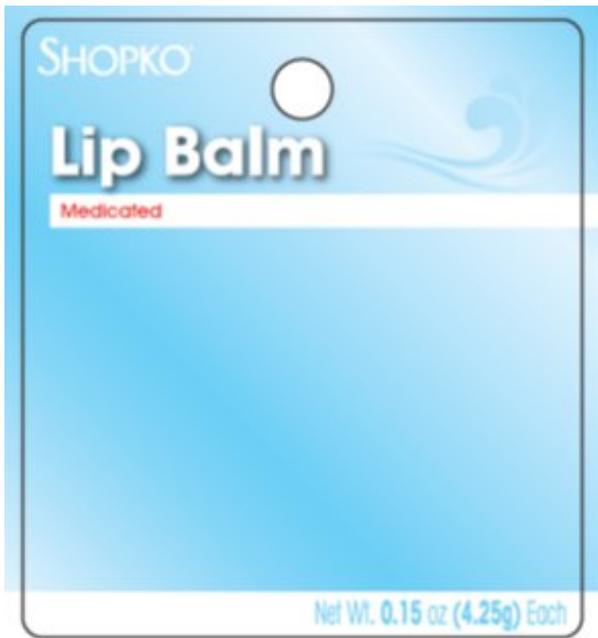
#### **Directions**

Apply liberally and evenly as needed. Children under 2 years of age: ask doctor before use.

#### **Inactive Ingredients**

Beeswax, Camphor, Cetyl Alcohol, Flavor, Ispropyl Myristate, Lanolin, Menthol, Methylparaben, Mineral Oil, Octyldodecanol, Oleyl Alcohol, Ozokerite, Phenol, Phenyl Trimethicone, Propylparaben, Stearyl Alcohol, Water

#### **Package/Label Principal Display Panel**



## SHOPKO MEDICATED LIP BALM

petrolatum stick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:370 12-737
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	41 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
CERESIN (UNII: Q1LS2UJO3A)	16 mg in 1 g
APIS CERANA WORKER SECRETION (UNII: PRG8653U8K)	6 mg in 1 g
OLEYL ALCOHOL (UNII: 172F2WN8DV)	6 mg in 1 g
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	5 mg in 1 g
OCTYLDODECANOL (UNII: 461N1O614Y)	9 mg in 1 g
LANOLIN (UNII: 7EV65EAW6H)	4 mg in 1 g
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	3 mg in 1 g
CETYL ALCOHOL (UNII: 936JST6JCN)	3 mg in 1 g
LIGHT MINERAL OIL (UNII: N6K5787QVP)	3 mg in 1 g
MENTHOL (UNII: L7T10EIP3A)	.60 mg in 1 g

### Product Characteristics

Color	WHITE	Score	
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<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MENTHOL	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:370 12-737-02	4.25 g in 1 CYLINDER		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/11/20 13	

**Labeler** - Shopko (023252638)

**Registrant** - Shopko (023252638)

### Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		80 18 24756	MANUFACTURE(370 12-737) , LABEL(370 12-737)

Revised: 7/2013

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