

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

### **Winco**

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

#### **Uses**

Helps prevent and temporarily protects dry, chapped or windburned lips.

#### **Warnings**

For external use only

Stop use and ask a doctor: If rash or irritation develops and lasts for more than 7 days.

When using this product: avoid contact with eyes. Rinse with water to remove.

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

#### **Directions**

Apply liberally and evenly as needed. Reapply as needed.

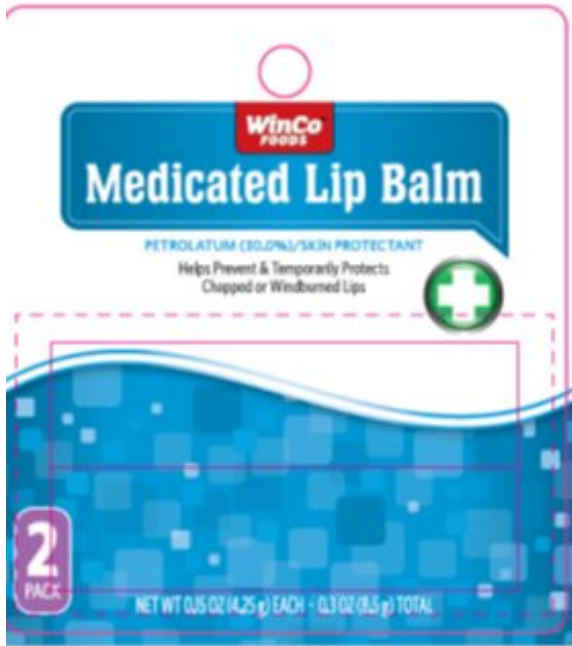
Children under 6 months of age: Ask a doctor before use.

#### **Inactive Ingredients**

Mineral Oil, Ozokerite, Microcrystalline Wax, Flavor, Cereson, Tocopherol.

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

Front of Card



Back of Card



## WINCO MEDICATED LIP BALM

petrolatum stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67091-251
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	30.0 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	39 mg in 1 g
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	3.00 mg in 1 g
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	24 mg in 1 g

### Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-251-30	1 g in 1 CONTAINER; Type 0: Not a Combination Product	01/02/2015	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/02/2015	

**Labeler** - Winco (056098817)

**Registrant** - OraLabs (801824756)

## Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(67091-251) , LABEL(67091-251)

Revised: 1/2022

Winco